Supreme Court, U.S.
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No. _____

In The

# Supreme Court of the United States

J.T. BRADLEY, et al.,

*Petitioners,*

v.

UNITED STATES OF AMERICA,

*Respondent.*

**On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Third Circuit**

## PETITION FOR A WRIT OF CERTIORARI

JOHN J. CUMMINGS, III, ESQ.
FRANK D. DUDENHEFER, JR., ESQ.
*Counsel of Record*
CUMMINGS, CUMMINGS & DUDENHEFER, A.P.L.C.
416 Gravier Street
New Orleans, LA 70130
Telephone: (504) 586-0000
Facsimile: (504) 522-8423

BARRY G. REED, ESQ.
ZIMMERMAN, REED, P.L.L.P.
901 North Third Street, Suite 100
Minneapolis, MN 55401
Telephone: (612) 341-0400
Facsimile: (612) 341-0844

DAVID A. VESEL, ESQ.
LAW OFFICES OF DAVID A. VESEL, P.A.
8212 Creedmoor Road, Suite 101
Raleigh, NC 27613
Telephone: (919) 844-0610
Facsimile: (919) 844-0620

*Counsel for Petitioners*

COCKLE LAW BRIEF PRINTING CO., (800) 225-6964
OR CALL COLLECT (402) 342-2831

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## QUESTIONS PRESENTED

I. Whether or not the United States Court of Appeals for the Third Circuit erred in ruling that Food, Drug and Cosmetic Act Section 510(k) determinations by the FDA involve government action as a matter of choice rather than actively prescribed by statute and regulation, and that the judgment involved is grounded in social, economic or political policy which the discretionary exception to the Federal Tort Claims Act (FTCA) is designed to shield in circumstances where the FDA ignored its own policies and procedures and engaged in misconduct and accompanied by possibly criminal conduct (bribery) on the part of certain FDA employees.

II. Whether or not the Court of Appeals for the Third Circuit erred in refusing to remand these proceedings to the District Court with instructions to lift the stay of all discovery against the Government for the specific purpose of permitting Petitioners to conduct *limited* discovery concerning further FDA misconduct which resulted in the illegal approval of the formerly rejected "pedicle screws," now resubmitted with only the cosmetic name change "long bone screws." Petitioners below believe that such discovery will show that because of such misconduct, the Government is not entitled to assert the discretionary exception to the Federal Tort Claims Act (FTCA).

## PARTIES TO THE PROCEEDING

The Appellants in the United States Court of Appeals for the Third Circuit (Plaintiffs in the District Court) were:

Those individuals are fully identified in the Opinion of the Third Circuit Court of Appeals filed August 31, 2001 at pages 1 through 20 of the Opinion (App. 1 through App. 20)

The Appellee in the United States Court of Appeals for the Third Circuit (Plaintiffs in the District Court) was:

The United States of America

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## PETITION FOR A WRIT OF CERTIORARI

Petitioners, J. T. Bradley, et al., respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Third Circuit.

## OPINIONS BELOW

The Opinion of the United States Court of Appeals for the Third Circuit filed August 31, 2001, is reported at 264 Fed. 3rd 344 (3rd Cir. 2001). It is reproduced at App. 1-41.

The Order of the United States District Court for the Eastern District of Pennsylvania, dated October 12, 2000, is reproduced at App. 42-66.

The Order of the United States Court of Appeals for the Third Circuit, November 21, 2001 denying Plaintiffs' Sur Petition for Panel Rehearing with Suggestion for Rehearing *En Banc* is reproduced at App. 67-68.

## JURISDICTION

The United States Court of Appeals for the Third Circuit, issued its opinion on August 31, 2001. Petitioners filed a Sur Petition for Panel Rehearing with Suggestion for Rehearing *En Banc* which was denied on November 21, 2001. The supervisory jurisdiction of this Court is invoked under 28 U.S.C. § 1254.

## STATUTORY AND REGULATORY PROVISIONS INVOLVED

21 C.F.R. § 807.87
21 C.F.R. § 807.100
21 U.S.C. § 351(f)(1)
21 U.S.C. § 351(i)
21 U.S.C. § 360(c)

The relevant portions of these provisions are reprinted at App. 69-72.

## STATEMENT

Several hundred recipients of pedicle screw fixation devices have filed numerous actions against the United States under the Federal Tort Claim Act ("FTCA"), 28 U.S.C. §§ 1346(b) & 2671, *et seq.* Their complaints (substantively mirror images) allege that due to a failure to exercise reasonable care, the Food and Drug Administration (the "FDA") negligently granted various manufacturers 510(k) clearance to market certain pedicle screw fixation devices which were not "substantially equivalent" to any predicate device and which lacked sufficient data to establish safety and effectiveness. The complaints further allege that the FDA failed to follow its own policies, practices and procedures with regard to granting 510(k) clearance and knew or should have known that the 510(k)-cleared devices were being improperly marketed for use in pedicle screw fixation. It was further alleged that as a direct and proximate result of the FDA's negligence, manufacturers were permitted to introduce medical device components into the marketplace where they

were marketed by the manufacturers and used by physicians as pedicle screw fixation devices.

The United States filed a motion to dismiss for lack of subject matter jurisdiction. In Pretrial Order 1950 the district court dismissed in excess of five hundred actions filed under the Federal Tort Claims Act. An appeal was taken, oral argument was heard, and the Third Circuit issued an opinion affirming the Trial Court's Judgment. An application for rehearing and rehearing *en banc* was filed and denied on November 21, 2001.

## REASON FOR SEEKING REVIEW

The record below demonstrates clearly and convincingly that the FDA violated its own policies and procedures. As discussed *infra*, FDA personnel encouraged, directed and assisted the various device manufacturers in circumventing the existing regulations. As a result of this FDA involvement, medical device, pedicular instrumentation, found by the FDA to be unreasonably dangerous were, at the suggestion of the FDA, redesignated as long bone screws and plates, approved by the FDA as such, and placed into commerce. Thereafter, with the knowledge of the FDA, the various device manufacturers promoted the adulterated and misbranded usage in the cervical spine. The FDA turned a blind eye to this pervasive illegal conduct. At best, this evidence effectively precludes the FDA from auguring that its actions were discretionary and therefore not actionable under the Federal Tort Claims Act. At worst, this evidence requires remand to the District Court for additional discovery on

the issue of FDA misconduct, particularly since such discovery could very well disclose possible criminal conduct in the form of bribery of FDA officials.

If the Opinion of the Third Circuit is allowed to stand, there will be no means to hold the FDA accountable for its misconduct and failure to follow its own policies and procedures. Victims of such misconduct, possibly rising to the level of criminal conduct, will be injured at great costs to themselves, their families, and society. Without the intervention of this Court, the FDA will be rewarded for failing to act as a regulator as intended by Congress instead of being held accountable under the Federal Tort Claims Act.

* * *

Pedicle screw fixation devices are subject to the Medical Device Amendments ("MDAs") to the Food, Drug and Cosmetic Act ("FDCA"). 21 U.S.C. § 360(c) *et seq.* Under this law, the FDA is required to promulgate regulations classifying medical devices.

Pursuant to the MDA, there are three distinct device categories subject to regulation. Class I devices generally pose little or no threat to public health and safety. Class II devices are those which pose a greater risk to health. Class III devices are those which present a potential unreasonable risk of illness or injury. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 116 S.Ct. 2240, 2246, 135 L.Ed.2d 700 (1996); 21 U.S.C. § 360c. Under the MDAs, as the potential risk increases, so does the regulatory scrutiny. *Id.* Each class is subject to different degrees of regulation. Class I devices are subject to the general controls, which apply to all medical devices. *Id.* Class II devices are more likely to

cause harm if they are defective or misused, and so the FDA may subject them to "special controls," such as a specific labeling requirement. *Id.* Class III devices, such as pedicle screw fixation devices, are those that cannot be marketed until the FDA has found, after carefully reviewing clinical data, that the device presents reasonable assurance of safety and effectiveness. *Id.* This process is known as pre-market approval ("PMA"). *Id.* at 2246-47.

If a manufacturer wishes to generate the scientific data necessary to obtain pre-market approval and thereby market a Class III medical device, it may do so under the Investigational Device Exemption ("IDE") provisions of the FDCA, which permit experimental devices to be used in clinical trials under stringent conditions established and actively supervised by the agency. *In Re: Orthopedic Bone Screw Liability Litigation*, 159 F.3d 817, 819 (3rd Cir. 1998) (citing 21 U.S.C. § 360j(g)). When the FDA grants an IDE, the device is considered an "investigational device" which may not be promoted for commercial distribution or test marketed outside of the IDE. 21 C.F.R. § 812.7(a).

In certain circumstances, a manufacturer may market a Class III device without undergoing the extensive PMA process. The MDAs include a "grandfathering" provision which permits pre-1976 devices to remain on the market without FDA approval until such time as the FDA initiates and completes the requisite PMA. *Lohr*, 116 S.Ct. at 2247 & n.3; *see* 21 U.S.C. §§ 360c(c)(2)(C) & 360c(f)(1). With respect to new devices not in commerce prior to May 28, 1976, however, the MDAs provide that such devices are Class III devices which may not be introduced into commerce without pre-market approval unless one of two circumstances is present. 21 U.S.C. §§ 360c(c)(2)(C)

& 360c(f)(1). First, a post-enactment device may be introduced into commerce without pre-market approval if it is reclassified into Class I or II by the FDA in response to a reclassification petition pursuant to 21 C.F.R. § 860.1 *et seq.* & 21 U.S.C. § 360c. The FDA may not reclassify a device unless there is "valid scientific evidence . . . to support a determination that there is a reasonable assurance that the device is safe and effective for its conditions of use." 21 C.F.R. § 860.7(c)(1).

Second, to prevent manufacturers of grandfathered devices from monopolizing the market while new devices undergo the PMA approval process, and to ensure prompt introduction of improvements to existing devices, the MDA permits a manufacturer to introduce a new Class III device into interstate commerce without pre-market approval if it can show that the device is "substantially equivalent" to a pre-existing "predicate device" – one which was in commerce prior to May 28, 1976, or which was introduced thereafter and reclassified as a Class I or II device. *See Lohr*, 116 S.Ct. at 2247; 21 U.S.C. §§ 360c(c)(2)(C), 360c(f)(1) & 21 C.F.R. § 807.100. This procedure is known as the 510(k) pre-market notification process. *Lohr*, 116 S.Ct. at 2247. In order for the FDA to determine that a device is "substantially equivalent" under the § 510(k) process, the Agency must find that the new device has the same intended use as the predicate device, and that it possess the same technological characteristics or is as safe and effective as the predicate device.[1] *Id.* (citing 21 U.S.C. § 360c(i)(1)(A)).

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[1] It is important to understand that the essential character of a device is not determined by its physical characteristics, but

Alternatively, the FDA may issue an order declaring the device to be "not substantially equivalent", which means that the device may not be legally marketed unless it obtains pre-market approval. *See* 21 C.F.R. §§ 807.100(a)(1) & (a)(2). In any event, 18 U.S.C. § 1001 makes it a crime to make a fraudulent statement to a federal agency and 21 C.F.R. § 807.87(j) requires every pre-market notification to contain a statement that the information contained therein is believed to be truthful. *In Re: Orthopedic Bone Screw Liability Litigation*, 159 F.3d at 823.

Under the MDAs, it is unlawful for any person to sell a new medical device which has not received pre-market approval or which has not been reclassified as a Class I or II device or cleared as substantially equivalent to an existing predicate device under § 510(k) pre-market notification process. 21 U.S.C. § 351(f)(1)(B); 21 U.S.C. §§ 352(o), 360c(a)(1)(C), 360c(c), 360c(f)(1) & 360(e); *United States v. One Labeled Unit*, 885 F. Supp. at 1028. In fact, the sale of a device without such approval or clearance is considered unlawful adulteration and/or misbranding of the device in violation of the provisions of the FDCA. *Id.* Moreover, if a supplier promotes an

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by its "intended use" – the use to which the manufacturer or seller intends the device to be put. *See, e.g.*, 21 U.S.C. § 321(h); *Church of Scientology of Minnesota v. Department of Health, Education and Welfare*, 341 F. Supp. 563, 563-68 (D. Minn. 1971). Therefore, different intended uses for the same physical apparatus gives rise to different devices, each of which must receive pre-market approval or clearance. Accordingly, the intended use of a device specified by the person submitting a request to the FDA for market clearance delineates the scope of the FDA's review. *See* 21 C.F.R. § 814.20(b)(3)(ii); 21 C.F.R. § 807.87(e).

intended use which has not been approved or cleared by the FDA, he is guilty of adulteration and misbranding. *See* 21 U.S.C. §§ 351(f)(1)(B), 352(o). Similarly, where the agency grants an IDE to conduct clinical trials concerning an "investigational use" of a device, the commercial promotion of the device for that investigational use is unlawful and also constitutes adulteration and misbranding of the device. *See* 21 U.S.C. § 351(i) & 21 C.F.R. § 812.7.

The Petitioners allege injuries and damages caused by a Class III medical device, pedicular instrumentation consisting of screws and plates inserted into their lumbar spines. These devices were never granted clearance or approval by the FDA. As such they were illegally introduced into commerce. The record demonstrates that various manufacturers repeatedly asked for FDA approval of their pedicular instrumentation. Each time such a request was rejected. Finally, **at the suggestion of the FDA,** the manufacturers resubmitted various requests for 510(k) approval for sacral and long bone use using the Edwards Sacral Screw as a predicate device. Both the FDA and the manufacturers knew that there was no sufficient market for either the sacral screws or long bone screws and plates. The FDA and manufacturers did, however, recognize that there was an enormous market for pedicular instrumentation. The FDA understood that the clearances granted were but a Trojan horse which would be used to introduce pedicular instrumentation into the surgical community. The FDA knew that pedicular instrumentation would be promoted and made available to the surgical community. The FDA knew that such misbranded/adulterated usage was widespread, this instrumentation

had become standard but, the FDA failed to use its regulatory authority to halt its illegal promotion and usage.

The FDA has no discretion to allow the introduction and usage of a Class III device in the absence of approval or 510(k) clearance. In fact, it has the mandatory responsibility not to authorize usage in the absence of rigorous scientific testing or under the predicate device exception (510(k) clearance). The FDA violated its mandatory duty by advocating, promoting, and assisting in the design of a subterfuge so as to place pedicular instrumentation in the hands of spine surgeons. Secondly, it had a mandatory duty to see to it that pedicular instrumentation was not promoted to the spine community since such usage was illegal, adulterated and misbranded.

In cases such as these, this Court has adopted a two-stage inquiry. *Gotha v. United States*, 115 F.3d at 179 (citing *Berkowitz v. United States*, 486 U.S. 531, 536, 108 S.Ct. 1954, 1958, 100 L.Ed.2d 531 (1988)). "First, a court must consider if 'a federal statute, regulation or policy specifically prescribes a course of action for an employee to follow.' " *Id.* Thus, where the employee has no rightful option but to adhere to the statutory or regulatory directive, his or her conduct cannot properly be the product of judgment or choice and, there is no discretion in the conduct for the discretionary function exception to protect. *Id.* Second, in the absence of such a prescribed course of action, the court must determine whether the challenged conduct is the type which the discretionary function exception was designed to shield – *i.e.*, "the permissible exercise of policy judgment." *Id.* at 179 (quoting *Berkowitz*, 486 U.S.

at 536-37). Fundamentally, " '[t]he exception, properly construed . . . protects only governmental actions and decisions based on considerations of public policy.' " *Id.* (quoting *Berkowitz*, 486 U.S. at 537).

The Third Circuit has held that "[w]here the conduct of Government employees in implementing agency regulations requires only performance of scientific evaluation and not the formulation of policy, . . . the conduct is [not] immunized from judicial review as a 'discretionary function.' " *Griffin v. United States*, 500 F.2d 1059, 1066 (3d Cir. 1974). The FDA decisions here at issue concern whether certain medical devices are substantially equivalent to predicate devices and, therefore, are not required to undergo pre-market approval. Petitioners have alleged that certain Class III pedicle screw fixation devices were cleared by the FDA for marketing as substantially equivalent, after the FDA had earlier determined that these devices were not substantially equivalent to any predicate device.

In *Berkowitz* this Court held that under such circumstances the discretionary function exception to the FTCA does not apply. In *Berwovitz*, a minor who contracted polio after taking an oral polio vaccine brought an action, alleging that the Division of Biologic Standards ("DBS") of the National Institute of Health had wrongfully licensed the production of the polio vaccine and that the FDA had wrongfully approved release to the public of the particular lot of vaccine containing the plaintiff's dose. The Supreme Court examined whether the DBS issued a product license without first receiving required test data as provided in federal regulation and held that the discretionary function exception did not apply.

Similarly, Petitioners' allegations in the instant litigation that the FDA violated its own policy, practice and procedure with respect to substantial equivalence determination by granting 510(k) clearance for the Edwards Sacral Screw despite Zimmer's failure to provide sufficient or valid data to demonstrate that the device was substantially equivalent to, or as safe and effective as, a predicate device to achieve spinal fusion and correct various spinal conditions.

Petitioners specifically claim that the FDA granted 510(k) clearance to the Edwards device despite earlier recommendations and reports by FDA reviewers which:

> (1) described the many biomechanical differences between the Edwards Sacral Screw and alleged "predicate devices";
>
> (2) determined that the Edwards Sacral Screw presented new questions of safety and effectiveness;
>
> (3) explained that insufficient information was provided in the pre-market notification to establish that bone screws for sacral attachment of spinal fixation rods would be as safe and effective as currently accepted alternatives/procedures that achieve spinal fusion and correction of various spinal conditions;
>
> (4) identified numerous deficiencies and questioned the statistical significance of the clinical results reported by Dr. Edwards to substantiate the safety and effectiveness of the Edwards Sacral Screw; and

> (5) concluded that there were no substantially equivalent devices and that any extensive testing of the device should take place under an IDE.

Because Petitioners aver that the FDA granted 510(k) clearance to the devices at issue after determining that they were not substantially equivalent to a pre-amendment device, the discretionary function exception does not bar plaintiffs' claims.

For example, one such device, the ISF/Luque, device was obviously intended solely for use as a spinal fixation construct and, as such, clearly did not have the same intended use as the devices claimed by Danek to be "predicate devices" which were intended to be used solely in the repair and treatment of fractures of long bones, the pelvis and cancellous bone outside of the spine. In regard to the inquiry related to intended use, the FDA was allowed no discretion. The determination of intended use within the context of the § 510(k) applications was preeminent under the statutory scheme. As the Third Circuit Court of Appeals has recently noted:

> The use to which a device will be put is of critical importance in the regulatory scheme. A device that presents no risk of injury when employed for one purpose may present great risk of injury when employed for another. For this reason a § 510 (k) clearance will be issued only if a device is a substantial equivalent of a preexisting device used for the same purpose. Moreover, a device cleared under § 510(k) cannot lawfully be marketed for a use other than the use specified in the clearance. Thus, if such a device is marketed for another purpose, the

> manufacturer may be civilly and criminally sanctioned and the marketing enjoined.
>
> . . .
>
> . . . Under [the statutory] scheme, the FDA is the gatekeeper charged with the responsibility of protecting the public from unreasonable risks of injury from medical devices. A manufacturer of a new device has no access to the market for any purpose absent some kind of FDA approval. Because the degree of risk presented by any device is a function of the use to which it is put, the intended use is thus the central focus in the FDA review. Indeed, there is nothing more material to its determination of whether to grant access to the market.

*In Re: Orthopedic Bone Screw Liability Litigation*, 159 F.3d at 828 (citing 21 U.S.C. §§ 331, 332).

Furthermore, the FDA's decisions as to whether certain medical devices are substantially equivalent to predicate devices are not immunized from judicial review as a "discretionary function" under the alternative *Berkowitz* analysis applied by the Government because in these cases the conduct of FDA employees in implementing agency regulations regarding substantial equivalence determinations requires only performance of scientific evaluation and not the formulation of policy. *Griffin v. United States*, 500 F.2d 1059, 1066 (3d Cir. 1974). In *Griffin*, an action was brought against the federal government for injuries sustained by a woman who ingested an oral live virus polio vaccine. On appeal, the Third Circuit Court of Appeals held that the discretionary function exception

did not apply to the Government's negligence in releasing the vaccine lot for public use, in violation of a regulation governing neurovirulence testing of the vaccine. In doing so, Circuit Judge Rosen wrote:

> We acknowledge that under DBS' construction of the regulation, the implementation called for a judgmental determination as to the degree to which each of the enumerated criteria indicated neurovirulence in monkeys. The judgment, however, was that of a professional measuring neurovirulence. It was not that of a policy-maker promulgating regulations by balancing competing policy considerations in determining the public interest. Neither was it a policy planning decision nor a determination of the feasibility or practicability of a government program. At issue was a scientific, but not policy-making determination as to whether each of the criteria listed in the regulation was met and the extent to which each such factor accurately indicated neurovirulence.

*Griffin*, 500 F.2d at 1066.

The Third Circuit's analysis at issue here focuses on the Government's regulatory actions and how those actions impact patients who are instrumented with screws and plates in the sacrum, in long bones, and the lumbar spine. However, such a focus is wrong. The focus must be the duty owed by the Government to a patient subjected to pedicular instrumentation. By focusing on the victim of pedicular instrumentation, the Government's breach of its mandatory duties is self evident. But for the encouragement of the FDA, conspiring to introduce these illegal devices into the surgical community, and but for the failure of the FDA to prohibit such illegal

usages, these victims would never have been subjected to pedicular instrumentation.

Perhaps it could be argued that in granting sacral and long bone clearance, the FDA should not be held accountable for adulterated/misbranded usage in the lumbar spine. Perhaps in other contexts such an argument would have merit but here, such an argument would be specious. There was initially no market for screws and plates other than for pedicular insertion. The Government told the manufacturers how to manipulate 510(k) clearance so that pedicular instrumentation would become a medical fact. Once it became a medical fact, the FDA threatened but never took appropriate regulatory action to halt its illegal usage. The Government had no discretion. It had the mandatory duty to see to it that pedicular instrumentation did not find its way into the hands of spine surgeons without appropriate approval or clearance. It had the mandatory duty to halt its promotion for adulterated/misbranded usage. Here the Government had no discretion to do anything other than fulfill the mandatory duties imposed by Congress. It failed to do so and is thus answerable for its negligence to the Petitioners.

It was error to require that the Petitioners demonstrate a specific set of factual allegations underlying their theory of the case, while failing to recognize that the Petitioners, despite good grounds and diligent efforts, were unfairly prejudiced by the trial court denying such discovery. It was further error, under such circumstances, to refuse remand for the limited discovery requested below.

> "We express no opinion on the question whether a specific set of factual allegations supporting the contention that a government agency acted in an intentionally wrongful or criminal manner could also support a contention that the government's behavior was 'negligent or wrongful' within the meaning of the FTCA." (Opinion, Footnote 19).

The Panel below thus acknowledges the dilemma faced by the Petitioners. Without discovery, the Petitioners can never put before the Court the specific facts underlying the actions of the FDA which they reasonably believe will demonstrate actionable negligence, possibly rising to the level of criminal conduct, on the part of the Food and Drug Administration. As Mr. Cummings represented in the Trial Court:

> MR. CUMMINGS: Let me tell you, as an officer of the Court, at a bare minimum, I think I will be able to produce for the Court, after discovery, the fact that the head of the department, Dr. Nermal Mishra, met with representatives of the manufacturers. And in their presence discussed how concerned he was about the future. How distressed he was about the expense that he was facing in paying tuition for his children in college. That he did not like to travel unless it was to some place nice.
>
> We would be able to prove that manufacturers flew two senior employees in this division to a convention at the expense of the manufacturers, all while this was pending.

The comments by counsel were not made in a vacuum. Discovery in the matter entitled *In Re: Orthopedic Bone Screw Liability Litigation*, 159 F. 3d 819 (3rd Cir. 1998)

conducted against various manufacturing defendants disclosed evidence of substantial government negligence and misconduct. More particularly, the evidence showed that the Food and Drug Administration consistently rejected 510(k) clearance for pedicle screw devices but even while doing so, offered the manufacturers advice as to how these illegal devices might find their way into the market place as an adulterated/misbranded product. FDA senior officials consistently threatened the manufacturers with regulatory actions and penalties but did nothing. FDA reviewers, knowing these devices were on the market illegally, nonetheless turned a blind eye to the illegal promotion while at the same time offering various manufacturers editorial advice as to the content of the product manuals covering instrumented spinal surgery.

The Third Circuit Opinion characterizes these allegations as being cast "in generalized terms", concluding that "our treatment of these claims is of necessity, similarly generalized" (Opinion page 28). Lacking full discovery of the specific underlying factual predicate decimates the ability of the Petitioners to prove its theory of liability. The Petitioners cannot meet the burden required by the Panel, specific rather generalized facts without relief, i.e. remand for the purpose of limited discovery.

Curiously, when the original Motion to Dismiss was heard it appeared that the trial court was prepared to established a discovery program:

> "I mean AcroMed, Dr. Steffe and these others, you see what we need, I guess we have to have

like a discovery plan to say, just limited discovery".

*Transcript October 5, 2000 Hearing,* App. 73-74.

In Oral Argument before the Third Circuit the question was raised as to the effect allowing discovery in this case would have on other similar claims against the Government. Would remand here open the door for other tort victims to seek discovery in a "fishing expedition" format? The response was and is that this case is unique in that there is a body of evidence before the Court demonstrating liability on the part of the FDA. Here there is no mere suspicion of misconduct or negligence; here Petitioners are not engaged in a fishing expedition. Rather there is a factual predicate which gives credibility to the allegations made herein of negligence and misconduct. More to the point, such evidence shows that the FDA violated its own policies and procedures, acted negligently, and perhaps criminally, in permitting the introduction of pedicator instrumentation into the stream of medical commerce, and once in commerce, failing to take appropriate regulatory action to eliminate these illegal Class III devices from the market place.

Remand for discovery here would create no precedent. A ruling granting discovery would be limited to the facts unique to this case and the factual predicate of negligence and misconduct which warrant further discovery. Denial of discovery here will have a dramatic, negative effect on any victim's ability to maintain an action against the Government in circumstances in which the Government acted negligently, possibly criminally,

and certainly contrary to its own policies and procedures. Lack of discovery here would be to reward what the Petitioners believe is certainly negligence and possibly criminal conduct.

The Third Circuit Court finds that the district court committed no abuse of discretion in denying any discovery against the Government. The Petitioners respectfully submit that where, as here, there is underlying evidence demonstrating governmental negligence and misconduct, the denial of any discovery whatsoever is a de facto, self-evident abuse of discretion.

## CONCLUSION

This Court should grant the Petition for a Writ of Certiorari.

Respectfully submitted,

JOHN J. CUMMINGS, III, ESQ.
FRANK D. DUDENHEFER, JR., ESQ.
*Counsel of Record*
CUMMINGS, CUMMINGS & DUDENHEFER, A.P.L.C.
416 Gravier Street
New Orleans, LA 70130
Telephone: (504) 586-0000
Facsimile: (504) 522-8423

BARRY G. REED, ESQ.
ZIMMERMAN, REED, P.L.L.P.
901 North Third Street, Suite 100
Minneapolis, MN 55401
Telephone: (612) 341-0400
Facsimile: (612) 341-0844

DAVID A. VESEL, ESQ.
LAW OFFICES OF DAVID A. VESEL, P.A.
8212 Creedmoor Road, Suite 101
Raleigh, NC 27613
Telephone: (919) 844-0610
Facsimile: (919) 844-0620

*Counsel for Petitioners*

Filed August 31, 2001

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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Nos. 00-3899 through 00-3922, 00-3925 through 00-3977, 00-3982 through 00-3984, 00-3986 through 00-4019, 00-4021 through 00-4057, 00-4060 through 00-4095 and 00-4098 through 00-4109

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IN RE: ORTHOPEDIC BONE SCREW PRODUCT LIABILITY LITIGATION

J.T. Bradley and Kathy W. Bradley, Appellants in No. 00-3899

Regina M. Luellen and Eurston Luellen, Sr., Appellants in No. 00-3900

Randal Jon Uribe, Appellant in No. 00-3901

Mitchell H. Walker and Kim S. Walker, Appellants in No. 00-3902

Jose Morfin, Appellant in No. 00-3903

Mary K. Mullen Schmelter and Kurt Allen Schmelter, Appellants in No. 00-3904

Rita Jan McGill and Gary McGill, Appellants in No. 00-3905

Louis H. McDowell, Jr. and Patricia McDowell, Appellants in No. 00-3906

Edward Briscoe, Gloria Briscoe, Dale Lewis Tamborella and Angela Tamborella

Appellants in No. 00-3907

James E. Doiron and Katherine Doiron, Appellants in No. 00-3908

Jeannette Wade and Edwin Wade, Appellants in No. 00-3909

Leila Hartwell, William J. Hartwell, Jennifer J. Still and Robert Still

Appellants in No. 00-3910

Fitz A. Reid, Etta A. Reid, Lillie Aycock, David Lindsey Brook and Mary Jane Brook, Appellants in No. 00-3911

Gary L. Drake, David Louviere and Laura M. Louviere, Appellants in No. 00-3912

Andrew Jackson Key and Linda C. Key, Appellants in No. 00-3913

Paul David Schneider and Linda Gale Schneider, Appellants in No. 00-3914

Esperanza Prida and Jorge Prida, Appellants in No. 00-3915

Reyes Basilio and Consolacion Basilio, Appellants in No. 00-3916

Ruth Rogoff, Appellant in No. 00-3917

Juan Perez and Maria I. Perez, Appellants in No. 00-3918

Brian McPherson and Kim McPherson, Appellants in No. 00-3919

Audrey Collins, Appellant in No. 00-3920

Jessie H. Elliott, Jr., Appellant in No. 00-3921

Arvie Jernigan, Appellant in No. 00-3922

Lafiro Max Benavides and Irene Benavides, Appellants in No. 00-3925

John Workman, Appellant in No. 00-3926

Thomas Craig McGowan and Lori L. McGowan, Appellants in No. 00-3927

Max E. Dick, Sr., Appellant in No. 00-3928

Rhonda Renee P. Lawrence and William J. Lawrence, Appellants in No. 00-3929

Raymond C. Cummings and Barbara Ann Cummings, Appellants in No. 00-3930

Larry Dale Spooner and Terri Spooner, Appellants in No. 00-3931

William P. Arinder, Betty Arinder, Newman Hearn and Deena Reese, Appellants in No. 00-3932

Randy W. McKenzie and Kimberly Sue McKenzie, Appellants in No. 00-3933

Karen A. Dunn and Robert T. Dunn, Appellants in No. 00-3934

Bruce Austin and Frances Austin, Appellants in No. 00-3935

Joan Barton and Joseph Barton, Appellants in No. 00-3936

Joseph Collura and Josephine Collura, Appellants in No. 00-3937

Helene Phyllis Cohen, Appellant in No. 00-3938

Joanne Conley Brown, Appellant in No. 00-3939

Connie Ray Baxley, Jr., Angie Baxley, Dick Habour, Brenda Sue Harbour, Terry Glen Johnson, Sr., Gerald Dewayne Jones and Sherry Lynn Jones, Appellants in No. 00-3940

Jonathan Bruce Holley, Elise Holley, Jerry Frank Wetz and Alice Wetz, Appellants in No. 00-3941

Leverne Anthony, Individually, and as Administrator of the Estate of Joseph Douglas Anthony, Sr., Appellant in No. 00-3942

Fred B. Basham and Claudia F. Basham, Appellants in No. 00-3943

Stanley P. Eagle, Sr. and Ladonna M. Eagle, Appellants in No. 00-3944

Charles E. Porter, Sr., Carol Jourdan Porter, Raymond Richard and Goldie P. Richard, Appellants in No. 00-3945

Randall L. Metzler, Appellant in No. 00-3946

Lawrence Damion Hickey, Appellant in No. 00-3947

Patricia A. Orlick and Robert Orlick, Appellants in No. 00-3948

Kathy Stockdale and George Stockdale, Appellants in No. 00-3949

Phillip W. Worrell and Janice Ann Worrell, Appellants in No. 00-3950

John H. O'Connell and Patricia O'Connell, Appellants in No. 00-3951

Clifford Burt and Barbara Sue Burt, Appellants in No. 00-3952

Chester Allen Morris and Yolan Sybil Morris, Appellants in No. 00-3953

Salvatore Cali and Genie Cali, Appellants in No. 00-3954

Dean W. Devine and Theresa Devine, Appellants in No. 00-3955

Jason Leigh, Appellant in No. 00-3956

Shirley Baker, Appellant in No. 00-3957

Richard Cullen, Appellant in No. 00-3958

Aline Frances Sears, Albert James Sears, III, John L. Davis and Louise E. Davis, Appellants in No. 00-3959

Mary Alma Valdez and Alexander Valdez, Appellants in No. 00-3960

Anthony Wilbur Kyle and Dixie K. Kyle, Appellants in No. 00-3961

Edward Allen, Roxana Paulette Allen, Denise K. Walker, Allen K. Walker, Annette E. Freeman, Patsy Ruth Elrod Bell and John Richard Bell, Jr., Appellants in No. 00-3962

Hettie Rovenia Crescini, Benjamin J. Crescini, Sr., James Fussell, Sherry E. Fussell, Dale C. Hutchinson, Dollinda Hutchinson, James Paul, Martha Lou Smith Paul, Bobby Ray Smith, Alvy J. Smith and Martin Carroll, Appellants in No. 00-3963

Dorris E. Harrell and Margie L. Harrell, Appellants in No. 00-3964

Wesley F. Stokes and Linda Gail Stokes, Appellants in No. 00-3965

Derrill B. Manley and Cindy Manley, Appellants in No. 00-3966

Aubrey J. Ledger, Appellant in No. 00-3967

Edward G. Herrera, Individually and as Administrator of the Estate of Rosie A. Herrera, Appellant in No. 00-3968

William Daniel Stone, Appellant in No. 00-3969

Jerry Whitaker and Patricia G. Whitaker, Appellants in No. 00-3970

Rita Gariby and Jesse Rubio Gariby, Appellants in No. 00-3971

Patricia Armijo, Appellant in No. 00-3972

Vera L. Berrington and William J. Berrington, Appellants in No. 00-3973

Terri H. Gibbs, Arlene F. Parker and William Parker, Appellants in No. 00-3974

Allen J. Montecino, Jr. and Virginia Montecino, Appellants in No. 00-3975

Gloria Huntman, Appellant in No. 00-3976

John M. Russo and Karen Russo, Appellants in No. 00-3977

Charles Thomas Wahlquist and Tina Rachelle Wahlquist, Appellants in No. 00-3982

Sammy Melissa Case and Ronnie Case, Appellants in No. 00-3983

Robert Brozewicz and Denise Brozewicz, Appellants in No. 00-3984

Charles Parrott, Allan R. Whitlow, Dorothy Merle Manberg and Charles Manberg Appellants in No. 00-3986

Danny L. Harris, Sr. and Cathie B. Harris, Appellants in No. 00-3987

Earl Hicks and Debra Hicks, Appellants in No. 00-3988

Amy Foote Weaselbear, Individually and as Administrator of the Estate of Archie A. Weaselbear, Appellant in No. 00-3990

Laurie L. Coogler, Dennis K. Coogler, Pamela A. Underferth, Thomas M. Underferth, Billie A.M. King, Cecil C. King, James Roger Smith and Vermell M. Smith, Appellants in No. 00-3991

Steve L. Thompson, Appellant in No. 00-3992

Eulalio "Bobby" Adami, Coy R. Griffin, Sr. and Wilma Griffin, Appellants in No. 00-3993

Ronald Gene Penny and Teresa R. Penny, Appellants in No. 00-3994

Shirley A. Plott, Appellant in No. 00-3995

Joan McGhee, Appellant in No. 00-3996

Melvin G. Burks, Appellant in No. 00-3997

Michael Seman, Appellant in No. 00-3998

Ginger Bentley and Henry L. Bentley, Appellants in No. 00-3999

Katherine Celia, Appellant in No. 00-4000

Connie Amelia Corley, Appellant in No. 00-4001

Lonnie Lowe, Appellant in No. 00-4002

Robert J. Berglund, Leslie Ann Berglund, Bruce D. Bultman, Carol Ching Bultman, Gary L. Ewing, Janet Walker Ewing, Timothy Scott Rushing and Joan Mary Rushing Appellants in No. 00-4003

Nancy G. Brown and Ronald E. Brown, Appellants in No. 00-4004

Candace L. Mathes and Stanley M. Mathes, III, Appellants in No. 00-4005

Kathleen Burke and Earl Burke, Appellants in No. 00-4006

Clifford R. Swain and Savana G. Swain, Appellants in No. 00-4007

James C. Smith and Beverly D. Smith, Appellants in No. 00-4008

Alex A. Driggers and Margie Ann Driggers, Appellants in No. 00-4009

Isidora Fuselier, Albert J. Fuselier, Michael Lee Andrus and Mark A. Bullard, Appellants in No. 00-4010

Harry Alan Bowser and Ronda L. Bowser, Appellants in No. 00-4011

Michael D. Holloway, Appellant in No. 00-4012

Lillian Marchegianni and John Marchegianni, Appellants in No. 00-4013

Jerry DeWayne Harrison and Mary M. Harrison, Appellants in No. 00-4014

M. Mary Coleman, Appellant in No. 00-4015

Jessie Flores and Mary I. Frias Flores, Appellants in No. 00-4016

Kap Jong Lee and Sung Wan Lee, Appellants in No. 00-4017

Richard Fontenot, Peggy Sue Fontenot and Perry Bang, Appellants in No. 00-4018

Wallace Wade Prahser and Donna Prahser, Appellants in No. 00-4019

James W. Ervin, Jr., Appellant in No. 00-4021

Larry Hugh Gibson and Connie Marine Gibson, Appellants in No. 00-4022

Leonard Otis Smith and Hazel M. Smith, Appellants in No. 00-4023

J.P. Parker, Appellant in No. 00-4024

Bruce W. Shepherd and Lorene B. Shepherd, Appellants in No. 00-4025

James Toskes, Appellant in No. 00-4026

Priscilla Fontenot, Lester Joseph Fontenot, Lee Anna Scott, Arthur Scott, Jr. John Goodman, Gertrude Goodman, Janice Reed, David Reed, Deidre Guillory Barbara L. Comeaux and Leander Comeaux, Appellants in No. 00-4027

Marilyn A. Greiner and Emil D. Greiner, Appellants in No. 00-4028

Jamie Lee Samuels and Thad J. Samuels, Appellants in No. 00-4029

Merle L. Jensen, David Bernard Jensen and David Rounkles, Appellants in No. 00-4030

Melissa Ann Chandler, Appellant in No. 00-4031

Thomas Levon Jones and Beverly Jones, Appellants in No. 00-4032

Irene Portillo, Appellant in No. 00-4033

Theodore N. Helton and Josephine T. Helton, Appellants in No. 00-4034

Grant Edward Tingstrom, Cathy J. Carrick, David L. Carrick, Sr., John Shaver and Diana Shaver, Appellants in No. 00-4035

William D. Sipes and Thelma G. Sipes, Appellants in No. 00-4036

George Love and Rosemary Love, Appellants in No. 00-4037

Joseph Anthony Strange, Appellant in No. 00-4038

Frank L. Bowes and Lollie Bowes, Appellants in No. 00-4039

Bruce Anthony Davis and Mary Ann Davis, Appellants in No. 00-4040

Gaty M. Jones and Janice A. Jones, Appellants in No. 00-4041

Elizabeth Bablitz and August E. Bablitz, Appellants in No. 00-4042

Caridad Perez, Rogelio Perez, Michael Joseph Smith, Rebecca A. Smith and Maria C.P. Bezara, Appellants in No. 00-4043

Vall R. Williams and Zolla Williams, Appellants in No. 00-4044

Kimberly DeRose, Michael J. DeRose, Salvatore Babriele, Jr. and Sandee Gabriele, Appellants in No. 00-4045

Billy Hines and Brenda Hines, Appellants in No. 00-4046

Michael Scott Schirmer and Patsy Schirmer, Appellants in No. 00-4047

Denis Ray Dunlap, Bernadette Dunlap, George R. Wiley, Judy Mize Wiley, Jeffery Lynn Miller and Donna Miller, Appellants in No. 00-4048

Cynthia Jo Lackey and Joseph Lackey, Appellants in No. 00-4049

Marsha Stites, Appellant in No. 00-4050

James Joseph Morway and Kristie Jo Morway, Appellants in No. 00-4051

Sandy Price and Michael L. Price, Appellants in No. 00-4052

Robert Shehan and Cleta Shehan, Appellants in No. 00-4053

Theresa L. Fitzgerald and John Patrick Fitzgerald, Jr., Appellants in No. 00-4054

William G. Warthen, Appellant in No. 00-4055

Roy H. Dedman, Nicole Dedman, David P. Abeyta and Lorri S. Abeyta, Appellants in No. 00-4056

Carroll D. Harris and Sharon Kay Harris, Appellants in No. 00-4057

Jerry Dale Arnold, Bonnie Sue Arnold and Elizabeth Cullen Ohrum, Appellants in No. 00-4060

Jackie C. Crenshaw and Rosetta A. Crenshaw, Appellants in No. 00-4061

Linda Patten Hitchcock and Dennis A. Hitchcock, Appellants in No. 00-4062

Frans R. Dorris and Dianne Reichenbacher Dorris, Appellants in No. 00-4063

James Stroderd and Paula Stroderd, Appellants in No. 00-4064

Kathy Diane Young and Billy Dale Young, Appellants in No. 00-4065

Gregory H. Hardin, Appellant in No. 00-4066

Raymond Nolan, Jr., Appellant in No. 00-4067

Michael Galloway and Pat Galloway, Appellants in No. 00-4068

Frank L. Dachenhausen and Thelma I.F. Dachenhausen, Appellants in No. 00-4069

Carmine A. Cilella and Gabriella Cilella, Appellants in No. 00-4070

Ronald Leroy Lee, Linda Lee Castleberry and H.L. Castleberry, Appellants in No. 00-4071

David Onger, Appellant in No. 00-4072

James T. Livingston, Jacqueline A. Livingston, Ronald Wayne Dean, Nanni P. Dean, William E. Boyer, Sr, and Melanie Kay Boyer, Appellants in No. 00-4073

Kenneth Kulhanek, Appellant in No. 00-4074

Rosemary K. Barotti, Peter W. Barotti, Kathryn McBratney and Jeff McBratney, Appellants in No. 00-4075

Billy Holbrook and Sherrie Holbrook, Appellants in No. 00-4076

Robert Geib and Donna Marie Geib, Appellants in No. 00-4077

Joyce Ann Robichaud, As Administrator of the Estate of Ray Robichaud, Appellant in No. 00-4078

Jimmy Shoemaker and Annette Shoemaker, Appellants in No. 00-4079

Jose Luis Rivera, Concepcion Rivera, Roslyn Del Pradia Wilson and Henry E. Wilson, Sr., Appellants in No. 00-4080

Bertha A. Salazar Vasquez and Hector G. Vasquez, Appellant in No. 00-4081

Donald Lynn McKeown and Janice McKeown, Appellants in No. 00-4082

Pauline Strickland White and Henry Willis White, Appellants in No. 00-4083

Jerry Dale Lewis and Mary D. Lewis, Appellants in No. 00-4084

Opal A. Parham, Appellant in No. 00-4085

Hazel Dueitt Sweatt and Earl Lynn Sweatt, Appellants in No. 00-4086

Marilyn Fitzgerald, Appellant in No. 00-4087

Alice McKinnon Clayton, Appellant in No. 00-4088

Maria De La Cruz and Miguel Angel De La Cruz, Appellants in No. 00-4089

Barbara Ann Bruzer and Dale Eugene Bruzer, Appellants in No. 00-4090

Joseph Lee Castle and Sandra Collins Castle, Appellants in No. 00-4091

Patricia Ann Hill and William A. Hill, Appellants in No. 00-4092

Annie Ruth Fralick, Appellant in No. 00-4093

Thomas James Olsen and Gloria M. Olsen, Appellants in No. 00-4094

Linda Newberry and Dave Newberry, Appellants in No. 00-4095

Estate/Heirs of Sharon Alderman*, Estate/Heirs of Ralph C. Anderson*, Todd Anselmo, Judith E. Anselmo, Phil Barber, Janice M. Barmore, Julie P. Barrack, Daniel W. Bartelt, Robert E. Bennett, Lois K. Bergsjo, Andrew L. Barry, Rebecca J. Boe, Clairce E. Boggs, Barbara Kay Bremer, Pamela M. Brewster, Morton G. Brill, Lenore Brill, Alonzo Brown, Vicki J. Brusewitz, James Buresh, Betty Butler, John Butler, Arlene V. Carlson, Diane L. Cassidy, Dennis Cassidy, Julie A. Charette, Dale Charette, Brian K. Ciske, Denise Cook, Muriel A. Crowley, Lillie M. Dabney, Timothy J. Dickau, James Douglas, Cheryl M. Douglas, Leona S. Ehnert, Majorie A. Etzel, Daniel M. Etzel, Cary M. Femrite, Robert L. Fields, Elizabeth A. Fischman, Donald J. Flower, Scott Fullex, Dennis J. Gallagher, Michael A. George, Calvin W. Gilbo, Sr., Donna C.

Green, Sharon L. Griffin Eloy Guzman, Sr.*, Roberta E. Hammerlind, Patricia L. Heidelberger, Raymond C. Hermanson, Gail Hermanson, Mark W. Herrman, Cynthia Herrman, Judith I. Hughes, Reginald F. Hughley, Todd W. Illies, Michael W. Iverson, Gayle E. Johnson, Dale Johnson, Janice M. Johnson, Daniel Johnson, Peter H. Johnson, Peggy Johnson, Cindy Osborne Keim, Barbara A. Kern, Karen M. Klein, Katherine E. Koehler, Barbara J. Kunshier, Robert B. Kwasigroch, Estate/Heirs of Robert A. Laessig*, Estate/Heirs of Frances Laessig*, David G. Lewandowski, Donnie K. Lilly, Donald J. Lisk, Patricia A. Lilly, Nancy L. Lisk, Craig W. Locher, Jodi Locher, Patricia J. Mandli, Michael M. Martinson, Anthony Martorana, Jean J. Martorana, Lorraine B. Mathis, Ethel McClain, Michael R. McConnell, Donald R. McRae, Jacqueline E. McRae, Virginia A. McVicker, William McVicker, Wendell D. Meeker, Marjorie L. Melinski, Shirley A. Moen, Marcy Myers, Jean A. Ness, James Ness, Jack C. Nicholson, Kathleen L. Nicholson, Cheryl M. Novotny, Richard A. Novotny, Larry J. Novotny, Claudette M. Novotny, Dennis W. Olson, Margery Olson, Ronald W. Olson, Randy R. Otto, Joan A. Pasowicz, Joseph Pasowicz, Stephen E. Paxton, Lisa M. Lugo-Paxton, Frederick L. Peck, Tina J. Peck Estate/Heirs of George J. Pesek*, Estate/Heirs of Katherine H. Pesek*, Estate/Heirs of Eugene S. Prantner*, William Peters, Lucille L. Peterson, Suzanne R. Petrusic, Walter Petrusic, Robert J. Plaksy*, Sharon Plaksy*, Ratsy Rathke, Arlene E. Reed, Ronald Reed, Rick Reizer, Jeffrey Richie, Debra A. Richie, Ricky K. Romaine, Lloyd Rose, Larry S. Rudolph, Lee R. Rysdam, Marija Rysdam, Richard H. Salverda, Rosemary Schibley, Phillip

E. Schmidt, Margaret A. Schmidt, Jeanne E. Skarda, Raymond T. Sobotta, Lee A. Solomon, Michael J. Spartz, Glee H. Spartz, Steven G. Starker, Edward J. Tentis, Gerard A. Theis, George E. Toth, Barbara Toth, Victor Towler, Barbara J. Venne, Mary Weinstein*, Milo D. White, Stefanja Z. Wojtczak, Jay H. Wyttehove and John W. Zink, Sr. Appellants in No. 00-4098, (*Caption amended per Court's Order dated 8/27/01)

James D. Bitzer, Charity A. Bitzer, James A. Mortensen, Dennis Raymond, Marlene Raymond and Mary L. Yeager, Appellants in No. 00-4099

Douglas J. Callaway, Dana Callaway, Ronald R. Sivak, Ann M. Weiler and Norbert Weiler, Appellants in No. 00-4100

Richard E. Almquist, Patricia E. Almquist, Kathie L. Avery*, Charles W. Avery, Gerald T. Baron, Margaret L. Bennett, Geneva G. Bissonette, William D. Bolton Jr., Joan Bolton, Jeanne A. Borkowicz, Ronald J. Borkowicz, Mark A. Chapman, Arthur L. Cotter, Barbara A. Cotter, Lynda M. Dahl-Kocurek, Silviu Dan*, Estate/Heirs of James Domaszek*, George I. Florek, Jeanne Florek, Debra G. Fox Joseph Fox, Herman Haayer, Jr., Pamela Haayer, Darlene D. Halder, Robert A. Hayes, Leah J. Henkel, Donald E. Hereau, Dorothy J. Hereau, Steve C. Hesse*, Nancy Hesse*, Estate/Heirs of Judy Jolly*, Wayne Jolly*, Michael J. Kaiser, Jody A. Lagergren, Todd Lagergren, Lois J. Lenzo, Gale R. Mattison, Ruby R. Pabelick, Michael D. Platts, Kathy Platts, Richard A. Pynenberg, Donna Rau, Glenn Rau, Judith G. Richart, Robert Richart, Jeffrey Richie, Debra A. Richie, Robert L. Schmalfeldt, Lori J. Schmalfeldt, Lonnie C. Shelley, Sharon Shelley, Sharon L.

Swanson, Joan M. Valenty, Mary L. Yeager and Charles A. Zinn, Appellants in No. 00-4101

(*Caption amended per Court's Order dated 8/27/01)

Michael K. Bentley, Marlene E. Bergeron, Joyce A. Bushrod, Robert R. Burns, Hanna Cahsai, Gail R. Copeland, Faye R. Copeland, Denise Cook, Lillie M. Dabney, Becky L. Dykes, Jerome T. Engel, Robert L. Fields, Mark D. Frakes, Gina Frakes, George C. Gonzalez, Brenda Gonzalez, William A. Green, Martha J. Green, Lois A. Hartwig, David L. Hartwig, Charles W. Hughes, Deane M. Hughes, Robert J. Johnson, Joan Johnson, Eileen E. Kaiser, Cindy Osborne Keim, Allen Kline, Jeffrey A. Koch, Laura J. Kollmer, Chris J. Kollmer, Michael A. Lachapelle, Donald J. Lisk, Nancy L. Lisk, Mitchell Pezanoski, Mary Pezanoski, Kenneth E. Retkowski, Gayle Retkowski, Joseph P. Schoenborn, Dawn J. Shelton Darryl C. Shelton, Michael J. Spartz, Glee H. Spartz, Steven G. Starker, Danette T. Tellijohn, Richard A. Theisen, Michael Thompson, Victor Towler, Timothy P. Tucker, Mary Weinstein*, Theresa Bichler Wichman and Mark J. Wietzke, Appellants in No. 00-4102

(*Caption amended per Court's Order dated 8/27/01)

Holly Bair*, Walter Austin, Hubert W. Bellisle, Mary J. Bellisle, Andrew L. Berry, Marlene M. Biggins, Thomas Biggins, James J. Breen*, Thelma Breen*, Estate/Heirs of Robert J. Brown*, Vivian Brown, Karen R. Callahan, Cathleen A. Crandall, Albert A. DiCruttalo, III, John Doherty, Robert C. Duisen, Jr., Carla J. Ford, Dana W. Frank, Joann C. Frank, John C. Frank, Gail R. Frank, Estella Gamez,

Linda S. Gipson, Donald F. Goold, Joan M. Goold, Mitchell E. Grav, Carolyn M. Hendley, Theron Hendley, Timothy Hill, Patricia F. Kearns, Dorothy M. Kinn, Florence I. (Wong) Lakin, Valerie E. Lennon, Jack W. McGillivray, Beatrice McGillivray, Kurt R. Meintsma, Brenda L. Moorer, Tillman E. Olson*, Victoria M. Olson, Ruth H. Perkel, Malcolm Perry, Monica Perry, Jack Robinson, Gregory Rubbo, George N. Ruzynski, June Ruzynski, Anna M. Scully, Lee A. Scully, Scott Silva, Michael J. Spartz, Glee H. Spartz, Steven Staudt, Tracy Staudt, Allen R. Terry, A. Thorne, Sandy Thorne, Victoria L. Valente, Ralph Abagian, Judy M. Walker, Estate/Heirs of Gerald F. Wehler*, Marjorie Wehler, Frank J. Williams and Angie Williams, Appellants in No. 00-4103

(*Caption amended per Court's Order dated 8/27/01)

Christine M. Anderson, Oscar Bernal, Gail R. Copeland, Faye R. Copeland, Steve Ferguson, Cindy Osborne Keim, Robert LaBlanc, Melvin Martin, Brooke Meyers, Riley L. Norris, Joyce Norris, Daniel P. Monson, Janet Smith, Bob Smith, William J. Vlasek, Doris Vlasek, William Walkenbach, Paul B. Wall, Sandra Weaver and Judy M. Walker, Appellants in No. 00-4104

James D. Ash, Cynthia Ash, Estate/Heirs of Sharon Alderman*, James R. Ashley, Mary A. Aune, Holly Bair*, Edward Barnes, Donald L. Beckman, Debra S. Beckman Emma L. Bennike, Robert E. Bennett, Nancy L. Brett, Gregory Brett, Joyce A. Bushrod, Karen R. Callahan, Traci W. Chapman, Gail A. Christian, Dorsey W. Cole, Carla J. Colombo, Belinda M. Cook, Scott M. Daniels, Robert C. Degeest, Thomas K. Dillon, Jeanne M. Garchek, Cecil P. Gibby, Betty Gibby, Carolyn Gibson, Raymond A. Golden,

Estate/Heirs of Essie L. Goldsmith*, William A. Green, Martha J. Green, Bobby Harrison, Everett E. Hendrickson, Pat Hendrickson, Joan C. Hochbrunn, Thomas Hochbrunn, Bertha E. Hokkanen, John Hokkanen, Julie A. Hunt, Renee M. Janusz, Mary L. Johnson, Alan K. Johnson Thomas W. Keene, Rosalie G. Keene, Nancy J. Kellam, James Kellam, Paul W. Kelly, Gerald J. Kernan, Jeffrey A. Koch, Benjamin F. Korfe, John A. Kraus Jr., Karen J. Lyons, Donald Lyons, Jr., Estate/Heirs of Mae V. Martin*, Calvin Martin, Melvin Martin, Gary P. McFarland, Jody McFarland, Alan R. McGee, Virginia A. McVicker, William McVicker, Robert Mertens, Brooke Meyers, Catherine J. Muha, Harold Mulcare, Randy A. Murray, Tracy Murray, Maxine T. Narog, Steve R. Newman, Linda Newman, Randy R. Otto, Freddie L. Owens Paulina Pappas, John R. Pappas, Kay Parr, James H. Parsons, Janet S. Parsons, Estate/Heirs of Norman Persten*, Richard J. Pietrzak, Karla Pietrzak, Frances H. Popham, Ronald Richards, Wayne W. Richards, Debra Richards, Kathleen Richardson, Luis Rivera, Roland C. Roberts, Patricia Roberts, Rose M. Robinson, James F. Robinson, Michael S. Ryan, John C. Salas, Howard D. Sams, Marion A. Sams, David R. Scalise, Clarence I. Seaburg, Joseph A. Sherry, William J. Skobjak, Annette Skobjak, Beulah E. Skoog, Lee A. Solomon, David J. Stanoch, Denise A. Stanoch, Marlette C. Steinke, Kathryn L. Stout, Denzil L. Stout Michael D. Supple, Mary B. Supple, Danette T. Tellijohn, Gerrye W. Tippens, Jerry Tippens, Albert E. Topolski, Brian Vaughn, Tom E. Wadsworth, Estate/Heirs of Gerald F. Wehler*, Marjorie Wehler and Roberta Zimmerman, Appellants in No. 00-4105

(*Caption amended per Court's Order dated 8/27/01)

Donald Lombard, William C. McPhail and Estate/Heirs of Charles D. Reynolds* Appellants in No. 00-4106

(*Caption amended per Court's Order dated 8/27/01)

Joanne Benton, Michael Sita, Beverly Sita, Gregory Osburn, Joy Osburn, Kelly D. Cowan, James Smith, Judy Smith, John Horton, Sandra Horton, Geraldo Feregrino, Laura Feregrino, Phillis Driver, Julian Whitten, Debra Whitten, Deva Buttram, Edward Buttram, Henry J. Klein, Patricia LaBree, Amos Jenkins, Linda Jenkins, James H. Reske, Sr., Ned Johnson, Maxine Johnson, Paula Watkins, Eyssel Gurganus, Henry Gurganus, Victoria B. Jones, Kirby Tharrington, Betty M. Brantley, Phyllis Perry, Claude Perry, Mary Thatch, John Thatch, Leotha Forte, Phyllis Forte, Emily Ennis, Lilyn D. Taux, Dilcy L. Hall, Carlton Parris, Joseph Amos, Christopher Poole, Missouri Garner, Victor Garner and Cynthia Esposito, Appellants in No. 00-4107

Donna Marie Beauchemin, Aaron Wayne Calk, Debra Calk, Vincent Foster Cochran, Peggy Joyce Cochran, Mary N. Hix, John M. Hix, Nicholas Host, Debra Ann Host David S. Lambert, Donnalyn Acosta, Robert E. Lee, Kathi Lewis, Shirley Lewis, Roger W. Lovell, Brenda Kay Graves Lovell, Gilbert Martinez, Jr., Maria Martinez, Ralph M. Nielsen, Marie J. Nielsen, David Perry, Brian Quinn, Cheryl Ann Smith, Donald Smith, David L. Spottek, James Swisher, Richard Lynn Thornton, Paul Williams, Barbara Jean Wilson, B.E. Wilson, Catherine A. Wright, Michael A. Bloomfield, Leslie J. Bloomfield, Kathleen Burke and Earl Burke, Appellants in 00-4108

Sherry Adams, Daniel Ray Adams, Betty C. Alisouskas, Vincent F. Alisouskas Dwayne Junior Allen, Doylene Todd Allen, Richard Lee Allen, John D. Austin Tami Austin, Robert Lee Baker, Cecil W. Barnett, Glenda Mae Harper Barnett Vivian K. Basham, Arice M. Basham, Lucy Frances Bauman, Thomas Richard Bauman Sr., Michael Belliveau, Lisa Belliveau, David Benavidez, Teresa Garcia Benavidez, Betty Jean Bennett, Betty Joanne Benning, Anthony P. Bertrand Evelyn Sue Bertrand, James Charles Besch, Bernice Ann Lay Besch, Deborah Best Joseph C. Best, Ronald Coburn Billings, Tina Marie Billings, Patricia Ann Blackledge, Buddy W. Blackledge, Sr., John William Blasko, Daniel L. Blemke, Beulah A. Boatsman, Stanley Dale Boogs, Linda Carolyn Latham Boggs Lynn H. Boles, Juanita Frogge Boles, Aulpheda Bonner, Jimmy T. Bonner, Melton Jack Book, Charlotte Book, Dennis P. Borghesi, Gayle Borghesi, Dorothy H. Bower, Marvin Lee Bower, Lora A. Bower, Bonnie F.S. Brinegar, Rocio Mier Brodd Wayne M. Brodd, Agnes Jean Brothers, William L. Brothers, Marvin J. Brouillette, Sr., Mary Lois Brouillette, Edgar Steve Brown, Tina R. Miers Brown, Lynn Jimette Brown, Michael Lynn Brown, Leonard Bushnell, Katherine Bushnell, Larry G. Carlson, Pamela G. Carlson, Luis H.G. Casanas, Arvie L. Causey, Doyle E. Chamblee, Hilda M. Chamblee, James H. Chambless, Richard D. Chandler, Stephanie W. Chandler, Vyron Breen Cherry, Dana Delores Marvin Cherry, James L. Christina, Susan Y. Christina, Ethel Coffman, Dennis D. Compton, Jerri Sue Compton, Harry C. Conner, Sr., Melina J. Conner, Randall C. Corbello, Rita M. Corbello, James Cottrell, Lois Couvillion, Estine Covillion Peter L. Covert, Susan K. Covert, Rodger K. Cox, Edith Mills-Cox, Jack Craycraft, Phyllis

Craycraft, Timothy Cunningham, Jennifer Cunningham, Richard Daniel, Debra J. Daniel, Mark Dixon DeHaven, Robin Lynn DeHaven, Lou Ella DeVille, Ty Dwayne Dick, Audrey Ann Dick, Sally M.A. Dickinson, Richard Dickinson, James Doherty, Shirley L. Dollarhide, Gerald J. Dollarhide, Marion Domer, Valerie Domer, Janice Miller Dowdy, William E. Dowdy, Richard Drumheller, Patricia Ann Crane Dulny, Roberta N. Dunn, Eugene D. Dunn, Jr. Lisa Hoens Guest DuPont Aguillard, Joseph M. DuPont, Russell G. Einolander Phyllis Lynne Elliott, Randall C. Elliott, Roger Keith Emrick, Penny Jae Emrick, Judy Evans, Howard L. Evans, Fred Preston Cone Evatt, Sr., Trubee Laverne Evatt, Edith G. Fewell, John Thomas Fewell, Robert J. Firek, Kathleen Mary Firek, Mary Frances Flory, Theresa M. Foltz, Louis Foltz, George M. Fontenot, Juanita C. Fontenot, Wilbert Fontenot, Reata Fontenot, Selby Clyde Ford, Dorothy C. Ford, Cynthia A.O. Foxworth, Debbie Fredette, Ernest A. Freeman, Ellen R. Fretty, Earl J. Fruge', Susan Fruge', Mark D. Fuller, Rosalva Fuller, George E. Garcia, Sally A. Garcia, Maxine Joan Gardetto, David T. Gardner, Leo Gardner, Jr., Beverly Sue Gardner, Gertrude Gautreaux, Kimberlee Gavosto, Darrin Gavosto, Murry C. Gear, Claretta I. Getts Gear, Greg Gillum Jr., Ruth A. Gillum, Marietta L. Gjertsen, Brian Todd Glowka, Kristi L. Glowka Patricia Grant, Forrest Griffin, Judith A. Potthast Griffin, Eva Grimes, Jerry Grimes, John S. Hallmark, Sr., Wanda J. Michaels Hallmaker, Mark E. Hanson Brenda Hanson, David Earl Hardy, Gloria D. Brooks Hardy, Louis Edward Hatsfelt Sr., William Hayes, Linda E. Hayes, Patricia Henderson, Frank L. Herron Cassandra Herron, Marie Black Hinson, Robert Steven Hinson, Nelson Hoffpauir Rose

Marie Holder, Timothy L. Hurd, Brenda Hurd, Lanny Jackson, Dora Ann Jackson, Joseph J. Jarmasek, Sr., Barbara Jarmasek, Walter Jeane, Mary H. Jeane, Carol Elaine Jewitt, Michael H.A. Jewitt, Edward Grant Johnson, Hazel Ross Johnson, L.C. Johnson, Dixie Brannon Johnson, Edna Lee Jones, Merleyn C. Jones, Victor L. Jones, Sharon Jones, Earl Jordy, Jr., Anita Jordy, Robert Kaminski, Linda Kaminski, Richard D. Kidd, Marlene Kidd, Thomas V. Kilgore, Penny Kilgore-Thomas, Barbara L. King, Deryl D. King, Victor Clyde Knapp, Jr., Deborah Kay Knapp, George Alvin Knight, Linda Sue Knight, Mary Kroupa-Casey, Kevin P. Casey, Andrew D. Kubiczki, Mary Kubiczki, Joanne L. Kuci, Feta Hysen Kuci, James A. Kuhns, Clay Carlton Kutscher, Helen Lamontagne-Eddy, Leona Lapradd, Ronald D. Larabee, Peggy Larson, Everett Larson, Patsy A. Lehmann, Paul Alton Livingston, Darrell W. Logan, Rebecca Logan, Sylvia G. Loucks, John Foster Loy, James E. Malenfant, Suzanne M. Malenfant, Zetty Malone, John F. Manley, Carlene E. Mansfield, Richard Marble, Inda Marble, Gary M. Marks, Clara D. Marrs, Gordon Ray Marrs, Debra K. Martin, Lyle E. Martin, Sandra Mason, Floyd Mason, Jacqueline B. Mauldin, Arthur Lewis Mauldin, William Lee McDuell, Birdie J. McDuell, Kevin L. McGaw, Becky Anderson, Arthur James McHugh, Mary Ann McHugh, Tony McKnight, Alex Mercado, Joann Mercado, Rachel Miller, Anthony Miranda, James Felton Mitcham, Lynn Mitcham, Evelyn Marie Mitchon, Kenneth H. Moore, Linda A. Moore, Ronnie Moore, Marva Moore, Myra Helen Moreau, J.R. Moreau, Kathleen H. Morris, Richard Morris, Donald Bruce Mountjoy, Kathleen Connor, Paul Mouton, Patricia M. Mouton, Katheryn D. Mueller, Allan

G. Mueller, James Murphy, Beverly Blassingane Murphy, Robert E. Murphy, Bonnie Murphy, Kimberly Naglich, Mark T. Naglich, Steve A. Nave, Katherine L. Nave, Jerry W. Newman, Mary Newman, Max H. Nix, Marilyn Joyce Nix, Brigitte H. Noorlander, John A. Noorlander, George E. O'Bryant, Alice Lightly O'Bryant, Richard S. Parker, Sylvia Inez Parker, Bobby Pelfrey, Stanley Perlstein, Gerald W. Pettifield, Ronald Plesz, Velda B. Plesz, Carolyn Rene Posey-Bond, Robert Clayton Bond, Michael G. Queen, Janice G. Queen, Kenneth P. Rainwater, Darlene S. Rainwater, Vicki Diana Jarrell Ramey, Richard Dale Ramey, Janet Ranney, Donald H. Ranney, Deborah Dee Reimund, Terry Allen Reimund, Sheri Lynn Revers, James Revers, Sharon Rewis, John Rewis, Jr., Shelia A.H. Rinehart, Ellis W. Rinehart, Danny Lee Ringo, Debra Ringo, Joan K. Roberts, Tommy L. Roberts, Patricia Ann Roberts, Dexter Robinson, David L. Ross, Carol Ross, John Ryan, Lawrence W. Salminen, Teddy Salmon, Anita Joy Salmon, Keith Watson Sandeford, Donna Baird Sandeford, Michael J. Schlaikjer, Christina Lynn Schlaikjer, Carlton William Schmidt, Peggy R.U. Schrier, Marylyn Ann Schultz, Roy Schultz, Leo G. Scott, Sheila G. Scott, Louis Servin, Donna Servin, Steven R. Shafer, Janice Shafer, Jane L. Shoe, Mary Ann Shores, James B. Shores Tommie C. Shoulders, Lorraine Shoulders, Elton Son Shults, Thomas Dudley Sides, Rosa F. Silva, Heriberto Silva, Martin Simmons, Diane Dille-Simmons, William B. Skelton, Sr., Agnes Lucille Skelton, Darrell Slape, Miriam P. Slavich, Ivan L. Slavich, Alfred Andrew Smith, Martha Jane Smith, George Smith, Elizabeth F. Smith, James Roger Smith, Vermell McBride Smith, Terry Eugene Smith, Penny Talley Smith, Kevin G. Spencer, Nikki

Spencer, Charles F. Stacks, Sarah Jan Stacks, Jerry Stephenson, Brenda J. Stinson, Max E. Stinson, Paul H. Stockton Nancy E. Stockton, Margie A.B. Stone, Vernon Odell Stone, Richard W. Stull, Donna Wojtasinski Stull, William P. Sturgeon, Audrey M. Tallant, Roger Dennis Watkins, John Tarka, Lorriane A. Tarka, Michael Franklin Taylor, Denise King Taylor, Nicholas Tentzeras, Dwight H. Terrell, Billy P. Thaggard, Linda Thaggard, Frances E. Thibodeau, Larry Thomas, Annette Marie Thomas, James F. Thomason, Mark A. Thornton, Donna L. Bonin Thornton, Terina Smith Threadgill, Larry E. Threadgill, Jr., James E. Timberlin, Sr., Frank E. Tomlinson, Donna Elizabeth Tomlinson, Diane Elaine Tresfon, Dewey Ronald Tubb, Charlotte P. Tubb, Richard C. Tucker, Deborah S.B. Turner, Harry D. Turner, Virginia F. Turner, Wendell Turner, Sr., Brian P. Vannatta, Charles P. Votruba, Denise C. Votruba, Kenneth Wade, Dianna Wade, James C. Walston, Sr., Ethel Marie Walston, James A. Ward, Kathleen Ward, Sharon R. Ward, Bruce L. Ward, John Layton Webb, Clark Welcher, Sharyl Welcher, Marie D. White, James S. White, Donald Edward Wilder, Betty Jane Murray Wilder, Cecil Williams, Jane Watson Williams, M. Teresa Willis, Larry N. Wilson, Octavia Wilson, Stephen W. Wilson, Lisa Wilson, William C. Winders, Virginia Winders, Rondell Vernon Wood, Dolores Laverne Wood, Tracy L. Workman, Janine Lee Workman, Kristine E. Young, Charles Drake, Priscilla Fontenot, Lester Joseph Fontenot, Thomas C. McGowan and Lori L. McGowan, Appellants in No. 00-4109

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On Appeal From the United States District Court
For the Eastern District of Pennsylvania
(MDL No. 1014)
District Judge: Honorable Louis C. Bechtle

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Argued: June 28, 2001

Before: BECKER, *Chief Judge*, NYGAARD and REAVLEY,* *Circuit Judges*.

(Filed August 31, 2001)

John J. Cummings, III, Esquire
Frank C. Dudenhefer, Esquire
(Argued),
Cummings, Cummings &
Dudenhefer, A.P.L.C.
416 Gravier Street
New Orleans, LA 70130

Karen Codey-Hopkins, Esquire
Ronald S. Goldser, Esquire
Zimmerman, Reed, P.L.L.P.
901 North Third Street, Suite 100
Minneapolis, MN 55401

David A. Vesel, Esquire
Law Offices of David A.
Vesel, P.A.
8212 Creedmoor Road,
Suite 101
Raleigh, NC 27613

*Counsel For Appellants*

Stuart E. Schiffer, Esquire
Acting Assistant Attorney General

---

*Honorable Thomas M. Reavley, United States Circuit Judge for the Fifth Circuit, sitting by designation.

Michael Levy, Esquire
United States Attorney
Eastern District of Pennsylvania

Mark B. Stern, Esquire
Charles W. Scarborough, Esquire
(Argued)
Attorneys, Appellate Staff
Civil Division, Room 9611
U.S. Department of Justice
601 D Street, NW
Washington, DC 20530-0001
Margaret Jane Porter, Esquire
Chief Counsel
Patricia J. Kaeding, Esquire
Associate Chief Counsel
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

*Counsel For Appellee*

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## OPINION OF THE COURT

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REAVLEY, Circuit Judge.

This Federal Torts Claims Act (FTCA) claim against the Food and Drug Administration (FDA) for granting clearance to market certain types of pedicle screw fixation devices (referred to generally as bone screws) was dismissed by the District Court pursuant to the discretionary function exception to the FTCA.[1] Appellants contend here that this jurisdictional exception should not apply

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[1] 28 U.S.C. § 2680(a).

because FDA officials were guilty of misconduct in the process of granting the clearance, and because Appellants should have been given more opportunity to discover proof of that misconduct. Moreover, Appellants argue that, even if the discretionary function exception does apply to the aspect of the bone screw clearance process challenged in their suit – i.e., the clearance of bone screws based on their substantial equivalence to devices already on the market – the exception does not bar Appellants' claims because the FDA's substantial equivalence determination does not involve the requisite element of judgment and choice, and is not the type of policy-based decision that the exception is designed to protect. Because the record establishes the Court's lack of jurisdiction, we will affirm.

## BACKGROUND

Thousands of plaintiffs nationwide claim to have suffered injuries resulting from the surgical implantation of bone screws in their spines and have sued their doctors and the manufacturers of the screws; and, as is relevant here, some two hundred have also sued the federal government. These actions have been consolidated by the Judicial Panel on Multidistrict Litigation and transferred to the Eastern District of Pennsylvania as MDL No. 1014.[2]

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[2] The circumstances of this litigation have received more comprehensive attention elsewhere than is required in this appeal. *See, e.g., Buckman Co. v. Plaintiffs' Legal Comm.*, 121 S.Ct. 1012, 1015-16 (2001); *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 193 F.3d 781, 784-87 (3d Cir. 1999).

1. *Regulatory Process*

Its [sic] is undisputed that marketing of the bone screws is regulated by the Federal Food, Drug, and Cosmetic Act,[3] as amended by the Medical Device Amendments of 1976 (MDA).[4] At the time the lawsuits were filed, the FDA had classified the bone screws as Class III devices, a categorization reserved for devices presenting "a potential unreasonable risk of illness or injury."[5] Before Class III devices can be marketed, they must receive "premarket approval" from the FDA[6] or, alternatively, they must qualify for FDA clearance based on a substantial equivalence determination.[7] It is a criminal offense to introduce a Class III medical device into commerce without approval or clearance.[8]

Because premarket approval is a lengthy, formal, and thus costly process often involving clinical trials under FDA supervision,[9] most new Class III devices enter the

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[3] Federal Food, Drug, and Cosmetic Act of 1938, ch. 675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-397).

[4] Medical Device Amendments of 1976, Pub.L. No. 94-295, 90 Stat. 539 (codified as amended in scattered sections of 21 U.S.C.).

[5] 21 U.S.C. § 360c(a)(1)(C)(ii)(II).

[6] *Id.* § 360e(a).

[7] *Id.* § 360e(b)(1); *see also Buckman*, 121 S.Ct. at 1015-16 (describing the FDA approval process applicable to the bone screw and similar devices).

[8] *See* 21 U.S.C. § 331(a); *In re Orthopedic Bone Screw*, 193 F.3d at 786.

[9] *See generally* 21 C.F.R. pt. 812.

market through FDA clearance.[10] New Class III devices qualify for clearance when the FDA determines they are "substantially equivalent" to a legally marketed "predicate device" (usually a device that was marketed before the Medical Device Amendments went into effect on May 28, 1976).[11] The process by which this clearance is granted is known as the "§ 510(k) process," in reference to the relevant MDA section. The process requires submission of the following:

1. "[p]roposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use,"

2. "[a] statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement,"

3. "[a] statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted," and

4. "[a]ny additional information regarding the device requested by the [FDA] Commissioner that is necessary for the Commissioner to make a finding as to whether or

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[10] *See Medtronic Inc. v. Lohr*, 518 U.S. 470, 479-80 (1996) (citing D. Kessler, S. Pape, & D. Sundwall, *The Federal Regulation of Medical Devices*, 317 New England J. Med. 357, 359 (1987)).

[11] 21 U.S.C. § 360e(b)(1)(B).

> not the device is substantially equivalent to a device in commercial distribution."[12]

The FDA grants clearance through the § 510(k) process when the new device has the same intended use as the predicate device and the FDA determines that it possesses the same technological characteristics or is as safe and effective as the predicate device.[13]

2. *Appellants' Allegations*

In 1984, Zimmer Inc. applied for § 510(k) clearance for the Edwards Sacral Screw Device. After two rejections and the submission of additional supporting information, Zimmer was ultimately granted clearance. Appellants allege that the reasons for the FDA's reversal of position

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[12] 21 C.F.R. § 807.87; *see also Buckman*, 121 S.Ct. at 1016.

[13] *See* 21 U.S.C. § 360c(i)(1); 21 C.F.R. § 807.100(b). According to § 360c(i)(1), a device is "substantially equivalent" to a predicate device if it "has the same intended use as the predicate device" and if the FDA has found it:

> (i) has the same technological characteristics as the predicate device, or
>
> (ii) (I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including appropriate clinical or scientific data if deemed necessary by the Secretary or a person accredited under section 360m of this title, that demonstrates that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and effectiveness than the predicate device.

are unknown, and that the clearance decision was erroneous because the evidence presented to the FDA revealed no predicate device substantially equivalent to the Edwards screw on the market. Following this determination, the FDA granted § 510(k) clearance to other bone screws. Appellants allege these applications were granted due to the erroneous clearance of the Edwards screw. Appellants also claim that the FDA granted clearance to Danek Medical to market the IFS/Luque Device for non-spinal use when it knew or should have known that the screw was intended solely for spinal use. They allege that Danek first described the screw as the "Interpedicular Segmental Fixation System" but changed its name to "Warsaw Orthopedic Bone Plates" and "Warsaw Orthopedic Cancellous Bone Screws" after its initial § 510(k) application was denied. Along with the name change, Danek removed all references to use of the device in the spine, describing its application as only for long or flat bones. The FDA then granted clearance. Appellants make similar complaints regarding the § 510(k) process for some of the other screws. And furthermore, they allege that an FDA official proposed the idea of changing the intended use of the screws in order to obtain clearance and provided advice on circumventing FDA rules.

Appellants claim that the FDA's conduct in granting clearance for each of the screws was negligent, intentionally erroneous,[14] and in violation of its own policy. They further contend that this misconduct resulted in the marketing and subsequent use of the bone screws that

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[14] Plaintiffs-Appellants accuse FDA officials of dishonest and even criminal conduct.

ultimately injured them. The government argues that the discretionary function exception to the FTCA precludes Appellants' claims, regardless of their merit.

## DISCUSSION

### a.

Appellants first seek to get around the discretionary function exception by arguing that, because they have alleged that the FDA's conduct in clearing bone screws for the market was intentionally erroneous, and possibly even criminal, the exception is not applicable at all. In the Appellants' submission, the discretionary function exception was never intended to shield a government agency from liability for such dishonest and criminal conduct, and thus Appellants should be permitted to pursue their claims of intentional and criminal misconduct against the FDA without having to overcome the discretionary function bar. We are constrained to disagree.

Even prior to reaching the discretionary function exception issue, Appellants bear the burden of demonstrating that their claims fall within the scope of the FTCA's waiver of government immunity.[15] Under the FTCA, the federal government only waives its immunity for injuries "caused by the negligent or wrongful act or omission of any employee of the Government . . . under circumstances where the United States, if a private person, would be liable to the claimant in accordance with the law of the place where the act or omission

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[15] *See Cato v. United States*, 70 F.3d 1103, 1107 (9th Cir. 1995).

occurred."[16] As the quoted language makes clear, the FTCA does not itself create a substantive cause of action against the United States; rather, it provides a mechanism for bringing a state law tort action against the federal government in federal court. Thus, "the extent of the United States' liability under the FTCA is generally determined by reference to state law."[17]

To state a viable FTCA claim based on their allegations of intentional and possibly criminal misconduct on the part of the FDA in the § 510(k) clearance process, Appellants need to demonstrate that such conduct amounted to a "negligent or wrongful act or omission" for which a private individual would be held liable under applicable state tort law. Appellants, however, face several hurdles to making this showing. First, we have examined the face of Appellants' complaints, and note that the complaints do not appear to allege that the FDA's behavior amounted to intentional or possibly criminal misconduct. Rather, in their complaints, Appellants contend that the FDA acted negligently and in violation of its own policies and procedures.[18]

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[16] 28 U.S.C. § 1346(b)(1).

[17] *Reo v. U.S. Postal Serv.*, 98 F.3d 73, 75 (3d Cir. 1996) (quoting *Molzof v. United States*, 502 U.S. 301, 305 (1992)) (internal quotation marks omitted).

[18] In fact, even in their appellate briefing, Appellants continued to emphasize that the FDA's clearance decisions were wrongful because they were made negligently and in violation of the FDA's policies and procedures, and not because the FDA's behavior represented intentional misconduct or potentially criminal behavior. *See* Appellants' Opening Brief at 10 ("Plaintiffs allege that the FDA was negligent, careless, failed to

Even if we were inclined to read Appellants' complaints liberally as stating claims based on the FDA's intentional and potentially criminal misconduct, we do not believe that these claims fall within the scope of the FTCA's sovereign immunity waiver. Appellants have cast their allegations regarding the FDA's intentional misconduct and potentially criminal behavior only in generalized terms, and our treatment of these claims is, of necessity, similarly generalized. We do not believe that intentionally improper or even criminal behavior, in the abstract, constitutes the type of "negligent or wrongful act or omission" for which the FTCA grants a waiver of sovereign immunity.[19] Appellants have not pointed us to (and we could find no) precedent standing for this general proposition, and, mindful of the fact that a

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exercise reasonable care and violated its own policy, practice and procedure with respect to substantial equivalence determinations in granting the requests by various manufacturers [for] 510(k) clearance."). Accordingly, the government's brief did not deal with this issue. Appellants did argue that the stay of discovery imposed by the District Court should be lifted because Appellants believed that they would obtain evidence of the FDA's intentional and possibly criminal misconduct, but it was not until oral argument on appeal that Appellants contended that their allegations regarding the FDA's intentional or criminal misbehavior should prevent any application of the discretionary function exception to Appellants' claims.

[19] We express no opinion on the question whether a specific set of factual allegations supporting the contention that a government agency acted in an intentionally wrongful or criminal manner could also support a contention that the government's behavior was "negligent or wrongful" within the meaning of the FTCA.

government's waiver of its sovereign immunity must be construed narrowly,[20] we believe it is improper for us to conclude that Appellants' claims based on the FDA's allegedly intentionally dishonest and possibly criminal behavior fall within the scope of the FTCA's immunity waiver. Furthermore, to the extent that Appellants' claims have the state law analog necessary under the FTCA, we believe that the pertinent state cause of action is one for some type of intentional tort of fraud or deceit. Such intentional conduct, however, is explicitly exempted from the FTCA's waiver of sovereign immunity.[21]

b.

Appellants' claims do allege that the FDA acted negligently, and in violation of its own policies and procedures. This set of claims would fall within the FTCA's general waiver of sovereign immunity, and we must therefore determine whether the District Court's application of the discretionary function exception to these claims was correct.

In *Berkovitz v. United States*,[22] the Supreme Court held that the discretionary function exception applies when (1) the act involves "an element of judgment or choice" and

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[20] *See Clinton County Comm'rs v. EPA*, 116 F.3d 1018, 1021 (3d Cir. 1997) ("A waiver of immunity must be unequivocally expressed and is construed strictly in favor of the sovereign.") (internal quotation marks and citations omitted).

[21] *See* 28 U.S.C. § 2680(h) (stating that the FTCA does not apply *inter alia* to "[a]ny claim arising out of . . . misrepresentation, deceit").

[22] 486 U.S. 531 (1988).

(2) that discretion "is of the kind that the discretionary function exception was designed to shield."[23] This inquiry does not focus on anyone's subjective intent in the exercise of that discretion, however. Instead, the inquiry focuses on "the nature of the actions taken and on whether they are susceptible to policy analysis."[24]

Appellants assert that both prongs of the *Berkovitz* inquiry support their position. They argue that the discretionary function exception does not apply to the § 510(k) clearances because (1) the FDA improperly granted the clearances, violating statutory and regulatory duties that do not allow for the exercise of any discretionary judgment or choice, and (2) the § 510(k) process involves merely scientific tasks rather than the exercise of policy-based discretion such as the exception was designed to protect. We disagree.

Under *Berkovitz*'s first prong, "[t]he requirement of judgment or choice is not satisfied if a 'federal statute, regulation, or policy specifically prescribes a course of action for an employee to follow,' because 'the employee has no rightful option but to adhere to that directive.' "[25] FDA determinations concerning substantial equivalency are governed by 21 U.S.C. § 360c(i)(1) and 21 C.F.R. § 807.100(b), which explicitly grant the FDA discretion to require additional information "if deemed necessary" and to set standards for evaluation of safety and efficacy.

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[23] *Id.* at 536; *see also Gotha v. United States*, 115 F.3d 176, 179 (3d Cir. 1997).

[24] *United States v. Gaubert*, 499 U.S. 315, 325 (1991).

[25] *Id.* at 322 (1991) (quoting *Berkovitz*, 486 U.S. at 536.

Specifically, § 807.100(b) requires only (1) that the new device and the predicate device have the same intended use, (2) that the devices have the same technological characteristics or that data demonstrates the new device is as safe and effective as the predicate, and (3) that neither the Commissioner nor the courts have taken specific action against the new device.

Appellants contend that the FDA granted clearance for the screws even though it knew or should have known that screws had an altogether new intended use (namely, fixation to the vertebral pedicles of the spine), even though the screws had different technological characteristics, and even though the screws were not as safe or effective as the predicate devices. Appellants further allege that, by so doing, the FDA failed to perform the mandatory duties required by law for granting § 510(k) clearance, and thus did not exercise the judgment or choice necessary under *Berkovitz*'s first prong to trigger the discretionary function exception.

The government argues that the statutory and regulatory provisions grant it discretion to decide what information is relevant in the § 510(k) process. Moreover, it points out that no mandatory authority dictates how it should go about determining whether devices have the same intended use, same technological characteristics, or similar performance in safety and efficacy. Accordingly, the government contends that the § 510(k) process requires the FDA to make discretionary choices utilizing its expertise. We agree.

When § 510(k) applications are brought before the FDA, regulators must decide what data and other information is relevant, what is reliable, and how much is sufficient. Certainly in weighing evidence and comparing medical devices in this manner, the FDA utilizes judgment and choice. Appellants' suggestion that the FDA violated statutory and regulatory provisions is, in reality, a claim that the FDA's judgment is wrong. Because substantial equivalence determinations as well as the manner in which those decisions get made are functions committed to the discretion of the FDA, we will not second guess their outcomes. The first step of the *Berkovitz* test is met.

Next, Appellants argue under the second *Berkovitz* prong that the § 510(k) process involves merely scientific tasks rather than the exercise of policy-based discretion. They rely on language in *Griffin v. United States*[26] for the proposition that scientific decisions do not fall within this exception. But their reliance is misplaced. *Griffin* concludes that some scientific determinations or measurements may not implicate policymaking discretion, not that science-based decisions never involve policymaking.[27] Because the § 510(k) process implicates such considerations as safety, efficacy, and cost, *Griffin* is not applicable. Furthermore, we have previously questioned

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[26] 500 F.2d 1059, 1066 (3d Cir. 1974).

[27] *See id.* ("At issue [is] a scientific, but not policy-making, determination as to whether each of the criteria listed in the regulation was met and the extent to which each such factor accurately indicated neurovirulence.").

the continuing authority of *Griffin* in light of subsequent Supreme Court decisions.[28]

The FDA's regulatory judgment in the § 510(k) process is susceptible to policy analysis and therefore falls within the kind of discretion the exception is designed to protect. The § 510(k) process requires judgment regarding what evidence is relevant, how well that evidence demonstrates safety and efficacy, and what weight should be given conflicting evidence and opinions. Implicit in this judgment is the balancing of values such as safety and cost. Decisions made in this context reflect policy choices and cannot be categorized as ministerial. Thus the second step of the test is also met. The FDA's actions were protected by the discretionary function exception.

2. *Stay of Discovery*

The District Court stayed discovery in this case while it considered the government's motion to dismiss. Our standard of review of questions concerning the scope or opportunity for discovery is for abuse of discretion.[29] Appellants argue that the stay was improper and prevented them from uncovering evidence of wrongdoing by the FDA. But because Appellants' proposed discovery was aimed at supporting claims that, for the reasons stated in part 1.a, fall outside the FTCA, and because the District Court had no jurisdiction over these claims, it

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[28] *See, e.g., Smith v. Johns-Manville Corp.*, 795 F.2d 301, 309 (3rd Cir. 1986).

[29] *See Brumfield v. Sanders*, 232 F.3d 376, 380 (3rd Cir. 2000).

was appropriate to stay discovery. The District Court acted within its discretion.[30]

The judgment of the District Court will be AFFIRMED.

A True Copy:
Teste:

*Clerk of the United States Court of Appeals*
*for the Third Circuit*

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[30] *Cf. id.*

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

| | | |
|---|---|---|
| IN RE: ORTHOPEDIC BONE SCREW PRODUCTS LIABILITY LITIGATION | : | MDL DOCKET NO. 1014 |
| THIS DOCUMENT RELATES TO ALL ACTIONS LISTED ON THE ATTACHED EXHIBIT | : | |

**PRETRIAL ORDER NO. 1950**

**AND NOW,** TO WIT, this 12 day of October, 2000, upon consideration of argument of the parties and a hearing held before the court on October 5, 2000, IT IS ORDERED that the civil actions listed on the attached exhibit are DISMISSED.

The court stayed the civil actions listed on the attached exhibit pending disposition of the appeal of Pretrial Order No. 1600 before the United States Court of Appeals for the Third Circuit. *See* Pretrial Order No. 1679 (staying cases). Plaintiffs state that the allegations in the civil actions listed on the attached exhibit are identical to the allegations raised in the seven civil actions that were dismissed by Pretrial Order No. 1600. *Id.* at 1 n. 1. The appeal before the Third Circuit has been dismissed.

At the hearing held on October 5, 2000,the court heard defendant. the United States' (the "Government") motion to dismiss the stayed cases for the reasons stated in Pretrial Order No. 1600, which the court incorporates

herein by reference. Plaintiffs opposed the Government's motion and asserted the need for further discovery.[1] Plaintiffs essentially reiterate the arguments they had previously made in opposition to the Government's motion to dismiss the FTCA cases. *See* Pretrial Order No. 1600 at 18-24 (addressing Plaintiffs' arguments that their factual allegations made out cognizable claim under FTCA). Plaintiffs did not cite new law or raise new

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[1] In support of their motion for further discovery, Plaintiffs stated that Pretrial Order No. 1223, entered on December 29, 1997, stayed the discovery in the Federal Tort Claims Act ("FTCA") cases and that their motion for reconsideration of this Order had not been ruled on.

The court notes that on December 3, 1997, the Government moved to stay proceedings pending the court's resolution of the Government's motion to dismiss the FTCA cases. On that same date, Plaintiffs also moved to stay all AcroMed related FTCA cases. On December 29, 1997, Pretrial Order No. 1223 granted the Government's motion. Plaintiffs' motion for reconsideration sought to vacate the court's Order as respecting non-AcroMed related FTCA cases. Plaintiffs' motion argued that the court made an error of law because the Government failed to demonstrate hardship or inequity to justify the stay.

On April 15, 1998, the court held a hearing on all pending motions related to the FTCA cases, and, on November 3, 1998, Pretrial Order No. 1600 dismissed the FTCA cases. Plaintiffs did not file a motion for reconsideration of this Order, or assert the need for further discovery.

Likewise, no motion for reconsideration asserting new evidence or the need for additional discovery was filed after the court entered Pretrial Order No. 1679, staying the remaining FTCA cases pending the appeal of Pretrial Order No. 1600. The court finds that Plaintiffs' arguments were addressed in Pretrial Order No. 1600, which dismissed the FTCA cases. Thus, Plaintiffs' motion for reconsideration of Pretrial Order No. 1223 is DENIED AS MOOT.

instances of governmental conduct that would exempt Plaintiffs' claims from the discretionary function exception to the FTCA. Plaintiffs' allegations involve the FDA's exercise of discretion rather than the violation of any mandatory directive and Plaintiffs continue to seek to inquire into the subjective decision making involved in the 510(k) clearance process. As the court has stated previously, "the focus of the inquiry is not on the agent's subjective intent in exercising the discretion conferred by statute or regulation, but on the nature of the actions taken and on whether they are susceptible to policy analysis." *Id.* at 18 (internal citations and quotations omitted); *see also Fisher Bros. Sales, Inc. v. United States*, 46 F.3d 279, 284 (3d Cir. 1995) (citations omitted). The discretionary function exception applies to "the exercise or performance or the failure to exercise or perform a discretionary function or duty . . . whether or not the discretion involved be abused." 28 U.S.C. § 2680(a). Thus, for the reasons stated in Pretrial Order No. 1600, the court finds that Plaintiffs' claims are barred by the discretionary function exception and the civil actions listed on the attached exhibit are DISMISSED.

SO ORDERED.

/s/ Louis C. Bechtle, J.
LOUIS C. BECHTLE, J.

REPORT DATE: 09/06/00
CIVIL INVENTORY/SCHEDULING REPORT

CASE
NUMBER FILED

JUDGE: SECHTLE, LOUIS C.

OFFICE: Philadelphia

2:97cvO7583 BRADLEY, et al vs UNITED STATES OF AM.
12/15/97
NOS: P.I.: Product Liability

2:97cvO7584 LUELLEN, et al vs UNITED STATES OF AM.
12/15/97
NOS: P.I.: Product Liability

2:97cvO7585 URIBE vs THE UNITED STATES
12/15/97
NOS: P.I.: Product Liability

2:97cvO7586 WALKER, et al vs THE UNITED STATES
12/15/97
NOS: P.I.: Product Liability

2:97cvO7587 MORFIN vs UNITED STATES OF AM.
12/15/97
NOS: P.I.: Product Liability

2:97cvO7588 SCHMELTER, et al vs UNITED STATES OF AM.
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NOS: P.I.: Product Liability

2:97cvO7589 MCGILL, et al vs THE UNITED STATES
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NOS: P.I.: Product Liability

2:97cvO7590 MCDOWELL, et al vs THE UNITED STATES
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2:97cvO7592 BRISCOE, et al vs THE UNITED STATES
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2:97cvO7593 DOINON, et al vs UNITED STATES
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NOS: P.I.: Product Liability

2:97cvO7594 WADE, et al vs UNITED STATES
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NOS: P.I.: Product Liability

2:97cvO7595 HARWELL, et al vs UNITED STATES OF AM.
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2:97cvO7596 REID, et al vs UNITED STATES OF AM
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NOS: P.I.: Product Liability

2:97cvO7597 DRAKE, et al vs UNITED STATES OF AM
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2:97cvO7598 KEY, et al vs UNITED STATES OF AM
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NOS: P.I.: Product Liability

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NOS: P.I.: Product Liability

2:97cvO7600 FRIDA, et al vs UNITED STATES
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NOS: P.I.: Product Liability

2:97cvO7601 BASILIO, et al vs UNITED STATES OF AM. et al
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NOS: P.I.: Product Liability

2:97cvO7602 ROGOFF vs UNITED STATES
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NOS: P.I.: Product Liability

2:97cvO7603 PEREZ, et al vs THE USA
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2:97cvO7604 MCPHERSON, et al vs USA
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2:97cvO7605 COLLINS vs THE UNITED STATES
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2:97cvO7606 ELLIOTT vs THE UNITED STATES
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2:97cvO7608 MURRAY, et al vs THE UNITED STATES
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2:97cvO7611 WORKMAN vs THE UNITED STATES
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2:97cvO7612 MCGOWAN, et al vs THE UNITED STATES
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2:97cvO7623 COHEN vs THE UNITED STATES
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2:97cvO7624 BROWN vs THE UNITED STATES
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NOS: P.I.: Product Liability

2:97cvO7625 BAXLEY, et al vs THE U.S.A.
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NOS: P.I.: Product Liability

2:97cvO7626 HOLLEY, et al vs THE UNITED STATES
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2:97cvO7627 ANTHONY vs THE UNITED STATES
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2:97cvO7698 MATHES, et al vs THE UNITED STATES
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2:97cvO7701 SMITH, et al vs USA
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2:97cvO7702 DRIGGERS, et al vs THE UNITED STATES
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2:97cvO7703 FUSELIER, et al vs USA
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2:97cvO7704 BOWSER, et al vs USA, et al
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2:97cvO7705 HOLLOWAY vs UNITED STATES OF AM
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2:97cvO7706 MARCHEGIANNI, et al vs UNITED STATES OF AM
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2:97cvO7707 HARRISON, et al vs UNITED STATES OF AM
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2:97cvO7708 COLEMAN vs THE UNITED STATES
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2:97cvO7709 FLORES, et al vs USA
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2:97cvO7710 LEE, et al vs USA
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2:97cvO7711 FONTENOT, et al vs THE UNITED STATES OF
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2:97cvO7712 PRAHSER, et al vs UNITED STATES OF AM, et al
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2:97cvO7724 CHANDLER vs THE UNITED STATES OF
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2:97cvO7726 PORTILLO vs THE UNITED STATES OF
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2:97cvO7759 HARDIN vs THE U.S.A., et al
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2:97cvO7760 NOLAN vs THE U.S.A.
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2:97cvO7763 CILELLA, et al vs THE U.S.A.
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2:97cvO7764 LEE, et al vs US OF AMERICA
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2:97cvO7766 LIVINGSTON, et al vs US OF AMERICA, et al
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2:97cvO7767 KULHANEK, et al vs US OF AMERICA
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2:97cvO7784 BRUZER, et al vs THE UNITED STATES OF
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NOS: P.I.: Product Liability

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10/02/98
NOS: P.I.: Product Liability

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IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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Nos. 00-3899 through 00-3922, 00-3925 through 00-3977,
00-3982 through 00-3984, 00-3986 through 00-4019,
00-4021 through 00-4057, 00-4060 through 00-4095,
00-4098 through 00-4108 and 00-4109

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IN RE: ORTHOPEDIC BONE SCREW
PRODUCT LIABILITY LITIGATION

---

**Present**: BECKER, Chief Judge, MANSMANN,
SCIRICA, NYGAARD, ALITO, ROTH, McKEE,
RENDELL, BARRY AMBRO, FUENTES, and REAVLEY,*
Circuit Judges.

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**SUR PETITION FOR PANEL REHEARING
WITH SUGGESTION FOR REHEARING *EN BANC***

---

The petition for rehearing filed by Appellants having been submitted to the judges who participated in the decision of this Court, and to all the other available circuit judges in active service, and no judge who concurred in the decision having asked for rehearing, and a majority of the circuit judges of the circuit in regular active service not having voted for rehearing by the court *en banc*, the petition for rehearing is DENIED.

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* As to panel rehearing only.

BY THE COURT:

/s/ Richard R. Becker
Chief Judge

DATED: NOV 21 2001
[Illegible]/cc: JJCS KJCH CWS
FCDS DAV

[Illegible]
Received and filed
11-21-01
Marcia M. Waldron
Clerk

**21 C.F.R. § 807.87. Information required in a premarket notification submission.**

Each premarket notification submission shall contain the following information:

* * *

(e) Proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. Where applicable, photographs or engineering drawings should be supplied.

(f) A statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement.

* * *

(j) For submissions claiming substantial equivalence to a device which has been classified into class III under section 513(b) of the act:

(k) A statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

**21 C.F.R. 807.100. FDA action on a premarket notification**

* * *

(b) FDA will determine that a device is substantially equivalent to a predicate device using the following criteria:

(1) The device has the same intended use as the predicate device; and

(2) The device:

(i) Has the same technological characteristics as the predicate device; or

(ii)(A) Has different technological characteristics, such as a significant change in the materials, design, energy source, or other features of the device from those of the predicate device;

(B) The data submitted establishes that the device is substantially equivalent to the predicate device and contains information, including clinical data if deemed necessary by the Commissioner, that demonstrates that the device is as safe and as effective as a legally marketed device; and

(C) Does not raise different questions of safety and effectiveness than the predicate device.

**21 U.S.C. § 360c. Classification of devices intended for human use**

**(a) Classes of devices**

(1) There are established the following classes of devices intended for human use:

* * *

**(C) Class III, Premarket Approval**

A device which because

(i) it (I) cannot be classified as a class I device because insufficient information exists to determine that the application of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and

(II) cannot be classified as a class II device because insufficient information exists to determine that the special controls described in subparagraph (B) would provide reasonable assurance of its safety and effectiveness, and

(ii)(I) is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or

(II) presents a potential unreasonable risk of illness or injury, is to be subject, in accordance with section 360e of this title, to

premarket approval to provide reasonable assurance of its safety and effectiveness.

---

**21 U.S.C. § 351. Adulterated drugs and devices**

A drug or device shall be deemed to be adulterated –

**(f) Certain class III devices**

(1) If it is a class III device

(A)(i) which is required by a regulation promulgated under subsection (b) of section 360e of this title to have an approval under such section of an application for premarket approval and which is not exempt from section 360e of this title under section 360j(g) of this title, and . . .

**(i) Failure to comply with requirements under which device was exempted for investigation use**

If it is a device for which an exemption has been granted under section 360j(g) of this title for investigational use and the person who was granted such exemption of any investigator who uses such device under such exemption fails to comply with a requirement prescribed by or under such section.

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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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| | | |
|---|---|---|
| IN RE: ORTHOPEDIC BONE SCREW PRODUCTS LIABILITY LITIGATION | : | MDL DOCKET NO. 1014 |
| | : | ALL CASES |

Philadelphia, Pa.
October 5, 2000

BEFORE HON. LOUIS C. BECHTLE, CH. J. EMERITUS

HEARING

* * *

[23] THE COURT: Are there any nonFDA people to be deposed?

MR. CUMMINGS: Thirteen, all of them in Rockville, Maryland.

THE COURT: Just 13 people?

MR. CUMMINGS: That's what we have.

THE COURT: You have information from other people, right?

MR. CUMMINGS: I have that with documents.

THE COURT: I mean you have gotten discovery that suggests for example someone made an offer of $80,000 or something, you just said something about an offer of a job.

MR. CUMMINGS: It has nothing to do with this. I already have that discovery.

THE COURT: Will the government be entitled to take discovery of those people?

MR. CUMMINGS: Sure, if they would like to.

THE COURT: Including AcroMed people?

MR. CUMMINGS: Buckman was the only one.

THE COURT: I mean AcroMed, Dr. Stefi and these others, you see what we need, I guess we have to have like a discovery plan to say, just limited discovery. It doesn't help me to simply cut out 13 people, that's all we want, while the government may

* * *

Supreme Court, U.S.
FILED
APR 24 2002
OFFICE OF THE CLERK

(2)

No. 01-1208

# In the Supreme Court of the United States

J.T. BRADLEY, ET AL., PETITIONERS

*v.*

UNITED STATES OF AMERICA

*ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT*

## BRIEF FOR THE UNITED STATES IN OPPOSITION

THEODORE B. OLSON
*Solicitor General*
*Counsel of Record*

ROBERT D. MCCALLUM, JR.
*Assistant Attorney General*

MARK B. STERN
CHARLES W. SCARBOROUGH
*Attorneys*

*Department of Justice*
*Washington, D.C. 20530-0001*
*(202) 514-2217*

5pp

## QUESTION PRESENTED

Whether the discretionary function exception to the Federal Tort Claims Act, 28 U.S.C. 2680(a), protects the Food and Drug Administration's decisions to clear certain pedicle screw fixation systems for marketing on the ground that they are "substantially equivalent" to predicate devices already on the market.

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# In the Supreme Court of the United States

No. 01-1208

J.T. BRADLEY, ET AL., PETITIONERS

*v.*

UNITED STATES OF AMERICA

*ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT*

## BRIEF FOR THE UNITED STATES IN OPPOSITION

### OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1-41) is reported at 264 F.3d 344. The opinion of the district court (Pet. App. 42-66) is unreported.

### JURISDICTION

The judgment of the court of appeals was entered on August 31, 2001. A petition for rehearing was denied on November 21, 2001 (Pet. App. 67-68). The petition for a writ of certiorari was filed on February 15, 2002. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

## STATEMENT

Petitioners claim that they suffered injuries from the implantation of orthopedic bone screws into the pedicles of their spines. They allege that the Food and Drug Administration (FDA) negligently cleared various pedicle screw fixation systems for marketing based on the conclusion that those devices were "substantially equivalent" to predicate devices already on the market. Seeking damages under the Federal Tort Claims Act (FTCA), 28 U.S.C. 2671 *et seq.*, petitioners filed suit against the United States. The district court and the court of appeals both concluded that the discretionary function exception to the FTCA bars petitioners' claims.

1. The Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.*, regulates food, drugs, cosmetics, and medical devices, and authorizes the FDA to enforce its requirements. The Medical Device Amendments of 1976 (MDA), Pub. L. No. 94-295, 90 Stat. 539, supplement the FDCA's medical device requirements. Under the MDA, medical devices are classified into one of three classes based on the risks to health that the devices pose and the controls that are necessary to provide reasonable assurance of the devices' safety and effectiveness. 21 U.S.C. 360c(a) (1994 & Supp. V 1999). Class I devices present the smallest risks to health and are subject to regulation through "general controls." 21 U.S.C. 360c(a)(1)(A). Class II devices are potentially more harmful. They are subject to both general controls and additional "special controls" that the FDA may impose. 21 U.S.C. 360c(a)(1)(B). Class III devices present the greatest risks to health and therefore are subject to the strictest regulation. 21 U.S.C. 360c(a)(1)(C)(ii)(II). All devices

first marketed after 1976 are initially deemed to be Class III devices. 21 U.S.C. 360c(f)(1) (1994 & Supp. V 1999).

Before a Class III device may be introduced into the market, a manufacturer generally must obtain a "premarket approval" (PMA) from the FDA. 21 U.S.C. 360c(a)(1)(C), 360e(a). To obtain a PMA, a prospective manufacturer must submit information to the FDA that provides reasonable assurance that the device is safe and effective for its intended use. 21 U.S.C. 360c(a)(1)(C), 360e(a) and (c); 21 U.S.C. 360e(d) (1994 & Supp. V 1999); 21 C.F.R. Pt. 814. "The PMA process is ordinarily quite time consuming because the FDA's review requires an 'average of 1,200 hours [for] each submission.'" *Buckman Co.* v. *Plaintiff's Legal Comm.*, 531 U.S. 341, 344-345 (2001) (quoting *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 477 (1996)).

A grandfathering provision permits Class III devices that were on the market before the MDA's enactment to remain on the market until the FDA initiates and completes a rulemaking requiring the submission of a PMA. 21 U.S.C. 360e(b)(1)(A). In order to prevent grandfathered manufacturers from monopolizing the market, the MDA allows other manufacturers to distribute competing devices if they show through a premarket notification process that they are "substantially equivalent" to predicate devices already on the market. 21 U.S.C. 360e(b)(1)(B). That premarket notification process is known as the "Section 510(k) process," which refers to the section of the FDCA codified at 21 U.S.C. 360(k) (1994 & Supp. V 1999). A device is "substantially equivalent" to a grandfathered device if it "has the same intended use as the predicate device," 21 U.S.C. 360c(i)(1)(A) (Supp. V. 1999), and the FDA finds that it "has the same technological characteristics as the

predicate device," or that it "has different technological characteristics," but the information submitted "demonstrates that the device is as safe and effective as a legally marketed device." 21 U.S.C. 360c(i)(1)(A)(ii) (Supp. V 1999). See *Buckman*, 531 U.S. at 345 (describing Section 510(k) process).

2. Petitioners are individuals who had bone screw devices implanted in the pedicles of their spines. Alleging that they suffered injuries because of those devices, petitioners filed thousands of individual suits against the manufacturers of the devices. Among other things, petitioners alleged that various manufacturers made fraudulent representations to the FDA concerning the intended uses of the devices and that the devices were thus improperly given market clearance. See *Buckman*, 531 U.S. 346-347. Although the Third Circuit initially held that petitioners' "fraud-on-the-FDA" claims could proceed, see *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 159 F.3d 817 (1998), this Court recently held that the claims "conflict with, and are therefore impliedly pre-empted by, federal law." *Buckman*, 531 U.S. at 348.

In addition, petitioners asserted tort claims against the United States in which they alleged that the FDA improperly granted clearances under Section 510(k) for various bone screw devices. The United States moved to dismiss petitioners' claims on the ground that they are barred by the discretionary function exception to the FTCA, 28 U.S.C. 2680(a), and the district court granted the motion. Pet. App. 42-66. Consistent with a prior order dismissing petitioners' claims, the court explained that petitioners' current "allegations involve the FDA's exercise of discretion rather than the violation of any mandatory directive and [petitioners] continue to seek to inquire into the subjective decision

making involved in the 510(k) clearance process." *Id.* at 44.

3. The court of appeals affirmed the district court's dismissal of the claims against the United States. Pet. App. 1-41. The court of appeals first rejected petitioners' attempt "to get around the discretionary function exception" by arguing that the FDA had engaged in intentional or criminal misconduct. *Id.* at 33. The court found that the "complaints do not appear to allege that the FDA's behavior amounted to intentional or possibly criminal misconduct." *Id.* at 34. Even assuming that petitioners had alleged "intentionally improper or criminal behavior" by the FDA, the court emphasized that such conduct would not generally "constitute[] the type of 'negligent or wrongful act or omission' for which the FTCA grants a waiver of sovereign immunity." *Id.* at 35. Finally, the court noted that the most pertinent state law analogue for petitioners' claims is an action "for some type of intentional tort of fraud or deceit," which "is explicitly exempted from the FTCA's waiver of sovereign immunity." *Id.* at 36 & n.21 (citing 28 U.S.C. 2680(h)).

The court next addressed petitioners' claims that the FDA acted negligently. Employing the two-part test for application of the discretionary function exception set out in *Berkovitz* v. *United States*, 486 U.S. 531, 536-537 (1988), the court first considered whether the challenged FDA decisions involve "an element of judgment or choice." Pet. App. 36-39 (quoting *Berkovitz*, 486 U.S. at 536). The court concluded that the FDA's substantial equivalence determinations under the Section 510(k) process involve judgment or choice because FDA regulators "must decide what data and other information is relevant, what is reliable, and how much is sufficient." *Id.* at 39.

The court also held that the FDA's decisions under the Section 510(k) process satisfy the second part of the *Berkovitz* test—they involve judgment "of the kind that the discretionary function exception was designed to shield." Pet. App. 37 (quoting *Berkovitz*, 486 U.S. at 536). In so holding, the court rejected petitioners' argument that "the § 510(k) process involves merely scientific tasks rather than the exercise of policy-based discretion." *Ibid.* The court noted that the Section 510(k) process requires the FDA to balance considerations such as safety and efficacy, and thus the FDA's judgments under that process "reflect policy choices." *Id.* at 40. Finally, the court held that the district court did not abuse its discretion in denying petitioners' requests for discovery. *Ibid.*

**ARGUMENT**

The decision of the court of appeals is correct and does not conflict with any decision of this Court or any other court of appeals. Accordingly, review by this Court is not warranted.

1. a. The FTCA is a limited waiver of sovereign immunity for certain tort actions against the United States. See 28 U.S.C. 1346(b), 2674. The discretionary function exception, which immunizes the United States from tort liability for discretionary policy choices made by its employees, is a significant limitation on that waiver of immunity. Under the exception, courts may not hold the United States liable for "[a]ny claim * * * based upon the exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the Government, whether or not the discretion involved be abused." 28 U.S.C. 2680(a).

An action comes within the exception if (1) "it involves an element of judgment or choice," and (2) the judgment "is of the kind that the discretionary function exception was designed to shield." *Berkovitz* v. *United States*, 486 U.S. 531, 536 (1988). The first step of the inquiry focuses on whether a "federal statute, regulation, or policy specifically prescribes a course of action" as to the decision at issue. *Ibid.* The second step of the inquiry focuses "on the nature of the actions taken and on whether they are susceptible to policy analysis." *United States* v. *Gaubert*, 499 U.S. 315, 325 (1991); see *United States* v. *S.A. Empresa de Viacao Aerea Rio Grandense (Varig Airlines)*, 467 U.S. 797, 814 (1984) (exception prevents "judicial 'second-guessing'" of decisions "grounded in social, economic, and political policy").

b. The court of appeals correctly applied the *Berkovitz* test in holding that petitioners' tort claims against the United States are barred. The court found that no specific, mandatory directives constrained the FDA's decisionmaking under the Section 510(k) process. Pet. App. 38-39. In addition, because "[t]he § 510(k) process requires judgment regarding what evidence is relevant, how well that evidence demonstrates safety and efficacy, and what weight should be given conflicting evidence and opinions," the court also held that the decisions made under the process are "susceptible to policy analysis" and involve judgment of the sort protected by the discretionary function exception. *Id.* at 40.

Petitioners do not seriously challenge the court of appeals' conclusions concerning the nature of the FDA's decisionmaking under the Section 510(k) process. Instead, petitioners argue (Pet. 3, 11-15) that "the FDA violated its own policies and procedures." Pet. 3. As in

the court of appeals, however, petitioners do not identify any specific directive that the FDA allegedly violated. Nor do petitioners explain why a violation of internal policies would necessarily strip respondent's actions of their discretionary character.

Petitioners argue that the FDA granted clearance for a certain device despite the manufacturer's "failure to provide sufficient or valid data to demonstrate that the device was substantially equivalent to, or as safe and effective as, a predicate device." Pet. 11. But the governing statutes and regulations give the FDA broad leeway in determining the quantity and quality of the data needed for substantial equivalence decisions. See 21 U.S.C. 360c(i)(1)(A) (Supp. V 1999) (requiring "appropriate clinical or scientific data if deemed necessary by the Secretary"); 21 C.F.R. 807.100(b)(2)(ii)(B) (same). Thus, the court of appeals correctly concluded that petitioners' argument "that the FDA violated statutory and regulatory provisions is, in reality, a claim that the FDA's judgment is wrong." Pet. App. 39.

Likewise, petitioners contend (Pet. 15) that the FDA violated a specific duty to take "appropriate regulatory action" to halt off-label uses of certain orthopedic bone screw devices in spinal surgeries. But the determination of what regulatory action is "appropriate" is clearly a discretionary judgment for the agency. As this Court recently recognized, the FDA has wide discretion in using the enforcement options at its disposal to combat suspected fraud, and it must be afforded sufficient "flexibility" to pursue many "difficult (and often competing) objectives." *Buckman*, 531 U.S. at 349; see *id.* at 350 (discussing with approval the FDA's policy regarding off-label use). Moreover, it is well-established that an agency's decision not to take

enforcement action is generally not subject to review under the Administrative Procedure Act (APA), 5 U.S.C. 551 *et seq.* *Heckler* v. *Chaney*, 470 U.S. 821, 831 (1985). Thus, the FDA's failure to take what petitioners believe was "appropriate" enforcement action against certain bone screw manufacturers cannot serve as the basis for tort liability under the FTCA. See *Moore* v. *Valder*, 65 F.3d 189 (D.C. Cir. 1995) (holding that prosecutorial decisions are generally protected under the discretionary function exception), cert. denied, 519 U.S. 820 (1996).

In addition, petitioners argue that decisions under the Section 510(k) process are not protected by the discretionary function exception because a substantial equivalence determination "requires only performance of scientific evaluation and not the formulation of policy." Pet. 13. The court of appeals also correctly rejected that argument. Pet. App. 39-40. The court explained that the Section 510(k) process implicates such considerations as safety and efficacy. *Id.* at 39. Thus, the court held that "[d]ecisions made in this context reflect policy choices and cannot be categorized as ministerial." *Id.* at 40.

The court of appeals' conclusion is supported by this Court's decision in *Gaubert*. The plaintiff in that case argued that the day-to-day "operational" decisions made by federal regulators who were running a bank were not protected under the discretionary function exception because the routine business decisions alleged to be improper (*i.e.*, hiring and firing consultants and mediating salary disputes) did not involve policy considerations. See *Gaubert*, 499 U.S. at 328. Emphasizing that "[d]iscretionary conduct is not confined to the policy or planning level," *id.* at 325, this Court rejected the argument that the government's actions

were not protected under the discretionary function exception simply "because they involved the mere application of technical skills and business expertise," *id.* at 331. Petitioners' argument that the FDA's determinations under the Section 510(k) process are not protected because they involve the application of scientific principles is similarly without merit. See also *GATX/Airlog Co.* v. *United States*, No. 99-36024, 2002 WL 598421, at *9 (9th Cir. Apr. 19, 2002) (holding that FAA's "equivalent strength" determinations in issuing airworthiness certificates were protected under the discretionary function exception despite arguments that such decisions involved "objective scientific standards").

Finally, petitioners point to no split of authority on the questions raised in the petition. In fact, petitioners do not cite any circuit court authority from outside the Third Circuit and principally argue that the Third Circuit's decision in this case deviates from prior Third Circuit precedent. Any such deviation, if it existed, would not warrant this Court's review. See *Wisniewski* v. *United States*, 353 U.S. 901 (1957) (per curiam).

2. Also contrary to petitioners' contentions (Pet. 15-19), the court of appeals correctly affirmed the district court's decision not to permit discovery on petitioners' claims of intentional or criminal wrongdoing by the FDA. The court of appeals found that the "complaints do not appear to allege that the FDA's behavior amounted to intentional or possibly criminal misconduct," Pet. App. 34, and reasoned that such conduct would in any event not generally "fall within the scope of the FTCA's immunity waiver," *id.* at 35-36. The court thus held that the "proposed discovery was aimed at supporting claims that * * * fall outside the FTCA." *Id.* at 40.

The petition does not challenge either the court of appeals' factual conclusion that petitioners' complaint does not assert claims of intentional wrongdoing by the FDA or the court's legal conclusion that the proposed discovery was not relevant to any viable claims under the FTCA. Instead, petitioners argue that a remand for discovery "would create no precedent" and "would be limited to the facts unique to this case." Pet. 18. The fact-bound and allegedly unique nature of the discovery issue in this case, however, only confirms that review by this Court is not warranted. See *Tiffany Fine Arts, Inc.* v. *United States*, 469 U.S. 310, 317 n.5 (1985) (noting that the Supreme Court will rarely disturb concurrent factual findings by an appellate court and a trial court); *Branti* v. *Finkel*, 445 U.S. 507, 512 n.6 (1980) (same).

## CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

THEODORE B. OLSON
*Solicitor General*

ROBERT D. MCCALLUM, JR.
*Assistant Attorney General*

MARK B. STERN
CHARLES W. SCARBOROUGH
*Attorneys*

APRIL 2002